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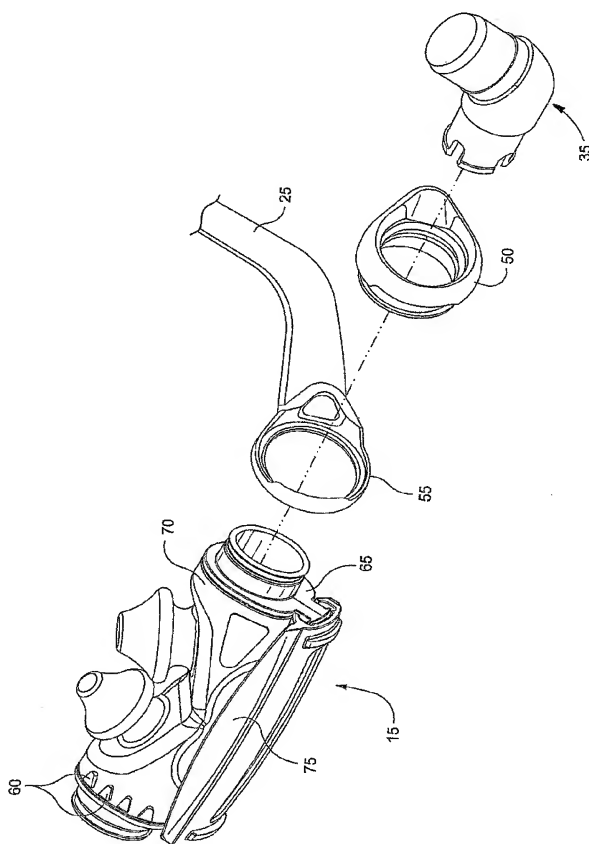
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(54) Title: NASAL ASSEMBLY



(57) Abstract: A nasal assembly (5) for delivering breathable gas to a patient includes a frame (65) having lateral connector (85), a cushion (70) with a pair of nozzles (175), and a clip (75) to secure the cushion (70) to the frame (65). The frame (65) includes a vent channel (90) and a plurality of vent holes (130). The frame/cushion includes structure (lugs/cut outs) to prevent the assembly of an unvented frame with an unvented cushion, for safety purposes. The frame (65) includes cored portions (160) that interface with corner lugs (185) provided on the cushion (70). A patient interface includes a frame, a cushion (nasal mask, nasal-oro mask, nozzles, etc.) and a vent assembly including a pattern of vent holes including at least two rows.



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NASAL ASSEMBLY

CROSS REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Design Application No. 29/258,084, filed April 14, 2006, and U.S. Provisional Patent Application Nos. 60/734,282, filed November 8, 2005, 60/758,200, filed January 12, 2006, 60/795,615, filed April 28, 2006, 60/819,626, filed July 11, 2006, and 60/838,442, filed August 18, 2006, each of which are incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a nasal assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-invasive Positive Pressure Ventilation (NPPV).

BACKGROUND OF THE INVENTION

[0003] Some nasal assemblies used in the treatment of SDB are designed for insertion into or adjacent the nasal passages of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the nasal assembly.

[0004] The nasal assembly generally includes a relatively rigid shell, e.g., a frame, and a pair of nozzles (which may be in the form of nasal pillows, nasal prongs, cannula, or nasal puffs) that are mounted on the rigid shell and structured to be inserted into or adjacent the nasal passages of the patient. The nozzles are usually held in place using a headgear assembly, the relatively rigid shell and headgear assembly being joined using some form of connector.

[0005] One form of known nasal assembly is described in U.S. Patent No. 4,782,832 (Trimble et al.). Trimble discloses a nasal puff assembly 20 that includes a nasal puff 22 adapted to be worn adjacent the nose of a patient, together with a harness assembly 24 adapted to be worn over the head of the patient. The harness assembly 24 is designed to operatively hold puff 22 adjacent and partially within the nasal passages of the patient.

[0006] The puff 22 is in the form of a generally Y-shaped rigid hollow plenum chamber 28 together with a pair of laterally spaced apart nares elements 30.

Adjustability of the nares elements 30 may be provided by rotatably mounting the elements 30 to the plenum chamber 28 and mounting the elements 30 in slots permitting selective lateral positioning of the elements 30 with respect to each other. Also, the harness assembly 24 may be adjusted to adjust the fit and seal of the nares elements 30 during use. That is, the force required to maintain a sufficient seal is directly associated with the force required to maintain a desired fit. Thus, adjustment of the fit or stability of the nasal assembly directly affects the seal, which can adversely affect patient comfort.

[0007] Other examples of nasal pillows or cannula mounted to rigid shells are disclosed in U.S. Patent Nos. 5,724,965 and 6,431,172.

[0008] A nasal mask assembly manufactured by Viasys, i.e., Spiritus, includes a plenum chamber with a pair of adjacent or laterally spaced nares elements. A harness assembly is engaged with the plenum chamber to adjust the fit and seal of the nares elements during use. Similar to Trimble, adjustment of the fit or stability of the nasal assembly directly affects the seal, which can adversely affect patient comfort.

[0009] A nasal mask assembly manufactured by InnoMed, i.e., Nasal Aire, includes a plenum chamber with a pair of adjacent or laterally spaced nares elements. The nares elements are structured to engage within the mucosal surfaces or internal passages of the patient's nose to maintain the nasal mask assembly on the patient's face and to provide a seal. See, e.g., U.S. Patent No. 5,533,506.

[0010] A nasal mask assembly manufactured by Stevenson Industries (see U.S. Patent No. 6,012,455), i.e., CPAP-Pro, includes a dental anchor, a platform, and air supply tubes having nasal pads, wherein the platform supports the air supply tubes. The dental anchor is sized to be engaged between the teeth in the patient's mouth so as to retain the assembly in place.

[0011] PCT Application Publication No. WO 00/13751 discloses a device that includes gas delivery elements positioned into engagement with the patient's nose by a mouthpiece fitted to the patient's teeth.

[0012] A common problem with known nasal assemblies, such as those discussed above, is patient comfort. For example, the prongs tend to irritate the patient's nose due to the tension applied by the headgear assembly that pulls the rigid shell and prongs towards the patient's nose.

[0013] Another problem is achievement of a sealing fit with the patient's nasal passages without sacrificing patient comfort.

[0014] Another problem is irritation of the inside of the patient's nostrils caused by contact with the prongs, e.g., an edge thereof.

[0015] Another problem is irritation of the inside of the patient's nostrils caused by air jetting (air flow irritation) from the prongs.

[0016] Another problem is adjustment of the nasal assemblies relative to the nose and/or head of the patient so as to accommodate various shapes and angles of patient's noses.

[0017] Still another problem is the direct association between sealing and stability forces that can affect patient comfort.

[0018] Still further nasal assemblies are known from the current assignee's co-pending U.S. Non-Provisional Application Nos. 11/101,657, filed April 8, 2005, and 10/781,929, filed February 20, 2004, each incorporated herein by reference in its entirety.

[0019] A further need has developed to even further reduce the noise associated with the washout or venting of exhaled gases from the breathing chamber.

SUMMARY OF THE INVENTION

[0020] One aspect of the invention is directed towards a nasal assembly, in particular an improved cushion/frame/vent/clip assembly having an improved frame, cushion, vent and/or clip component. The assembly may effectively reduce the noise associated with gas washout or venting of the patient.

[0021] Another aspect of the invention is to prevent the use of an old-style frame (which has no vent holes) with a cushion as described herein (which also has no holes).

[0022] Another aspect of the invention is directed towards a frame that is easy and inexpensive to manufacture.

[0023] Another aspect of the invention is directed to a frame with a vent channel and a plurality of vent holes, in which case it is not necessary to provide the cushion with such gas washout vent holes.

[0024] According to another aspect of the invention, the clip may have ribs to improve strength/stiffness, and/or to allow ease of grip. The clip may also have wings with compound curvature to help improve strength/stiffness.

[0025] Another aspect of the invention provides a nasal assembly for delivering breathable gas to a patient. The assembly includes a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein the frame includes a vent channel provided in the main body, the vent channel including a pair of side walls extending from the main body towards a base wall, said base wall including at least one vent hole.

[0026] According to another aspect of the invention, there is provided a nasal assembly for delivering breathable gas to a patient, comprising a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein the frame includes a plurality of vent holes, said vent holes being provided in two or more rows arranged such that the vent holes are offset from one another.

[0027] According to another aspect of the invention, there is provided a nasal assembly for delivering breathable gas to a patient, comprising a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein the frame includes longitudinal cushion channels to receive longitudinal edges of the cushion, at least one of said cushion channels including at least one cut out to receive a lug of the cushion upon assembly.

[0028] According to another aspect of the invention, there is provided a nasal assembly for delivering breathable gas to a patient, comprising a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein the frame includes a circumferential cushion channel provided to each said lateral side of the frame, said frame including a cored portion generally aligned with each circumferential cushion channel, said cushion including a corner lug to interface with each said cored portion.

[0029] According to another aspect of the invention, there is provided a nasal assembly for delivering breathable gas to a patient, comprising a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector, the frame including at least one vent hole; a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame; and a clip to secure the cushion to the frame, wherein the clip includes a vent window generally aligned with the at least one vent hole.

[0030] According to still another aspect of the invention, there is provided a patient interface for delivering breathable gas to a patient, comprising a frame; a cushion to communicate with a patient's airways in use, the cushion being coupled with the frame; and a vent portion including a plurality of vent holes, said vent holes being provided in two or more rows and the rows being arranged such that the vent holes are offset from one another.

[0031] Yet another aspect of the invention relates to a full-face mask frame including a main body having a longitudinal axis and a vent assembly provided to the main body. The vent assembly includes a plurality of holes arranged in at least one column. The at least one column is aligned with or parallel to the longitudinal axis.

[0032] Yet another aspect of the invention relates to a mask frame including a main body and a side frame portion provided on each lateral side of the main body. A vent assembly is provided to each side frame portion. Each vent assembly includes a plurality of holes arranged in a multi-column pattern and each column is vertically staggered with respect to one another.

[0033] Yet another aspect of the invention relates to a nasal assembly for delivering breathable gas to a patient. The nasal assembly includes a frame and a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use. The cushion is coupled with the frame. The cushion includes a size indicator, a series of position arrows, text, and/or a logo provided to one side of the cushion. The size indicator, series of position arrows, text, and/or logo are adapted to provide a visual cue to assist the patient in achieving correct alignment and orientation of the cushion and frame with respect to the patient in use.

[0034] Yet another aspect of the invention relates to a nasal assembly for delivering breathable gas to a patient. The nasal assembly includes a frame including a main body and a cushion including a pair of nozzles to communicate with nasal

passages of a patient's nose in use. The cushion is coupled with the main body of the frame. The frame includes a vent channel provided in the main body. The vent channel includes a pair of side walls extending from the main body towards a base wall. Each of the side walls includes a variable wall thickness along its length.

[0035] Yet another aspect of the invention relates to a nasal assembly for delivering breathable gas to a patient. The nasal assembly includes a frame and a cushion coupled to the frame. The cushion includes a pair of nozzles to communicate with nasal passages of a patient's nose in use. The frame includes a vent channel that leads to at least one vent hole. The vent channel is adapted to buffer and/or separate higher velocity and more turbulent air flow into and around the frame from an entrance to the at least one vent hole.

[0036] Yet another aspect of the invention relates to a mask frame including a main body including an aperture adapted to communicate with an elbow and a vent assembly provided to the main body. The vent assembly includes a plurality of holes arranged around the aperture.

[0037] Other aspects, features and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0039] Fig. 1 is a perspective view of a nasal assembly according to an embodiment of the present invention;

[0040] Fig. 2 is an exploded view illustrating a portion of the nasal assembly shown in Fig. 1;

[0041] Fig. 3 is a perspective view of a frame according to an embodiment of the invention;

[0042] Fig. 4 is a reverse perspective view thereof;

[0043] Fig. 5 is a front view thereof;

[0044] Fig. 6 is a rear view thereof;

[0045] Fig. 7 is a side view thereof;

- [0046] Fig. 8 is a top view thereof;
- [0047] Fig. 9 is a cross-sectional view along line 9-9 of Fig. 8;
- [0048] Fig. 10 is a cross-sectional view along a longitudinal axis of the frame, through one of the rows of vent holes;
- [0049] Fig. 11 is a perspective view of a cushion according to an embodiment of the present invention;
- [0050] Fig. 12 is a front view thereof;
- [0051] Fig. 13 is a top view thereof;
- [0052] Fig. 14 is a rear view thereof;
- [0053] Fig. 15 is a bottom view thereof;
- [0054] Fig. 16 is a front view similar to the front view of Fig. 12, but from slightly different orientation;
- [0055] Fig. 17 is a cross-sectional view along line 17-17 in Fig. 16;
- [0056] Fig. 18 is a left side view thereof;
- [0057] Fig. 19 is a right side view thereof;
- [0058] Fig. 20 is a perspective cross-sectional view along line 20-20 in Fig. 19;
- [0059] Fig. 21 is a perspective view of a clip according to an embodiment of the present invention;
- [0060] Fig. 22 is a reverse perspective view thereof;
- [0061] Fig. 23 is a front view thereof;
- [0062] Fig. 24 is a bottom view thereof;
- [0063] Fig. 25 is a rear view thereof;
- [0064] Fig. 26 is a side view thereof;
- [0065] Fig. 27 is a perspective view of a cushion subassembly according to an embodiment of the present invention;
- [0066] Fig. 28 is a top view thereof;
- [0067] Fig. 29 is a bottom view thereof;
- [0068] Fig. 30 is a rear view thereof;
- [0069] Fig. 31 is a side view thereof;
- [0070] Fig. 32 is a front view thereof;
- [0071] Fig. 33 is a cross-sectional view along line 33-33 of Fig. 32;
- [0072] Fig. 34 is a cross-sectional view along line 34-34 of Fig. 32;
- [0073] Fig. 35 illustrates a vent assembly according to another embodiment of the present invention;

- [0074] Figs. 36 and 37 illustrate a vent assembly according to another embodiment of the present invention;
- [0075] Figs. 38-44 illustrate various views of a mask frame including a vent assembly according to another embodiment of the present invention;
- [0076] Figs. 45-52 illustrate various views of a mask frame including a vent assembly according to another embodiment of the present invention;
- [0077] Figs. 53-55 are various views of a cushion assembly according to another embodiment of the present invention;
- [0078] Figs. 56A, 56B and 57 are various views of a frame of the cushion assembly shown in Figs. 53-55;
- [0079] Figs. 58-59 are cross-sectional views through line A-A of Fig. 57;
- [0080] Figs. 60-61 are cross-sectional views through line B-B of Fig. 57;
- [0081] Figs. 62-64 are various exploded views of the cushion assembly shown in Figs. 53-55;
- [0082] Fig. 65 is a side view illustrating correct orientation of the cushion assembly shown in Figs. 53-55 on a patient;
- [0083] Fig. 66 is a side view illustrating incorrect orientation of the cushion assembly shown in Figs. 53-55 on a patient;
- [0084] Fig. 67 is an exploded view of a nasal assembly according to another embodiment of the present invention;
- [0085] Figs. 68-75 are various views of a cushion assembly of the nasal assembly shown in Fig. 67;
- [0086] Figs. 76-83 are various views of a clip of the nasal assembly shown in Fig. 67;
- [0087] Fig. 84 illustrates a mask including a vent assembly according to another embodiment of the present invention;
- [0088] Fig. 85 is a schematic view of the vent assembly shown in Fig. 84;
- [0089] Figs. 86-87 illustrate an elbow according to an embodiment of the present invention; and
- [0090] Fig. 88 illustrates an elbow retaining clip according to an embodiment of the present invention, the elbow retaining clip adapted for use with the elbow shown in Figs. 86-87.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0091] The following includes a description of one or more illustrated embodiments of the present invention. Each illustrated embodiment includes features that may be used with and/or in the other embodiments, or with the embodiments and/or components described in U.S. Non-Provisional Application Nos. 10/781,929 and/or 11/101,657, as would be apparent to those of ordinary skill in the art. The general operation of the embodiments described herein is substantially identical to the operation of the embodiments detailed in USSN 10/781,929 and USSN 11/101,557, and therefore will not be repeated.

1.0 Overall Nasal Assembly

[0092] Fig. 1 illustrates a nasal assembly 5 according to an embodiment of the present invention. As shown in Fig. 1, nasal assembly 5 includes headgear 10 and a cushion assembly 15. Headgear 10 is designed to capture the crown of the patient's head. Adjustment of strap tension can be accomplished by pulling loose tabs 20 on the top of the head in opposite directions. The pulling direction is not aligned with the force the nozzle assembly applies to the patient. Therefore, the patient is more isolated from the strap adjustment forces. Yokes 25 provide stability to the sides. Yokes 25 retain at least a partial portion of the basic shape of headgear, which facilitates donning of the headgear. Headgear need not include adjustability toward front of the face, as all adjustment of headgear can be effected at the back or top of the head.

[0093] In the embodiment of Fig. 1, one end of the cushion assembly 15 is provided with a plug 30 and the other end is provided with a swivel elbow 35. The positions of the swivel elbow 35 and the plug 30 may be interchanged, according to preference, e.g., the typical sleeping position of the patient. An air delivery tube 40 is joined to the swivel elbow 35. The air delivery tube 40 may include a swivel connector and includes an end which also may be provided with a swivel connector. The end is provided with a source of pressurized gas.

[0094] As shown in Fig. 1, the elbow 35 is angled about 120° from the cushion assembly 15. This helps to keep the tube out of line of sight, to minimize pressure drop and to maintain the flexion point of tube as close to the face as possible. However, the elbow may have a typical 90° bend.

[0095] Fig. 2 is an exploded view of a portion of the nasal assembly 5 shown in Fig. 1, including the cushion assembly 15, yoke 25, seal portion 50 and elbow 35 (the other side of the cushion assembly is provided with a yoke, seal portion and an elbow or plug). The yoke 25 may include a yoke ring 55. The cushion assembly 15 may be adjustably rotated with respect to headgear, to a position which best fits the patient. The ring of the yoke associated with the other side of the headgear (not shown) may include an alignment marker that can be selectively aligned with one of a plurality of alignment markers 60 provided on the cushion.

2.0 Cushion assembly

[0096] Cushion assembly 15 includes a frame 65, a cushion 70 and a clip 75. Figs. 3-10 show the frame in isolation, Figs. 11-20 show the cushion in isolation, Figs. 21-26 show the clip in isolation, and Figs. 27-34 show the assembly of the frame, cushion and clip.

2.1.0 Frame

[0097] As shown in Fig. 3, frame 65 has a main body 80 and lateral sides. Each lateral side includes a lateral connector portion 85. Frame 65 is preferably made of molded plastic, e.g., polycarbonate and/or polypropylene.

2.1.1 Vent Channel

[0098] Main body 80 of frame is provided with a vent channel 90 defined by a base wall 92 and a pair of side walls 94. Vent channel 90 extends from an inside surface 95 of the main body toward the base wall 92. An upper portion 100 of the vent channel 90 is positioned in a plane just below the lowest point 110 of the inlet aperture 115 of lateral connector 85.

[0099] Side walls 94 converge towards one another in the direction of the base wall at a slight angle α (α), e.g., about 2-5 degrees, preferably 2 degrees. Each side wall 94 has a lower portion 120 that is provided to the base wall 92 along a radius of curvature RL of about 0.2-0.4mm, preferably about 0.3mm, and the upper portion 100 that is curved, e.g., with a radius of curvature RU of between about 0.5 to 1.5mm, preferably about 0.9 to 1.0mm. The width WS between the side walls is about 2-3mm, preferably about 2.6 mm. The width between the side walls increases in the direction of upper portion 100 due to the angle α (α), described above.

2.1.2 Vent Holes

[00100] Channel 90 is in communication with a plurality of vent holes 130, e.g., 6-60 vent holes, and preferably about 35-45 vent holes, although there could be more than 60 holes or less than 6 holes, depending on application. In the example of Fig. 5, there are 39 holes. Each vent hole 130 has a generally part conic shape, including opposed walls 135 that converge from a larger diameter to a smaller diameter, as viewed in the direction of exhausted gas. The walls 135 preferably converge at an angle beta (β), i.e., an included angle, of about 1-90 degrees, and preferably 2-8 degrees, and even more preferably about 5 degrees. Each wall preferably has a radius of curvature HR of about .15-.35mm, preferably 0.25mm.

[00101] Figs. 3, 5, 6 and 9 illustrate one possible vent arrangement that includes offset rows of vent holes. However, other arrangements are possible. For example, Figure 35 illustrates a portion of a vent assembly 300 having a plurality of holes 305, e.g., 5-10 holes or more, arranged in a pattern by three rows of holes 305. The center row includes one or more additional holes at each end thereof. The positioning of the assembly 300 is similar to that shown in Figure 3.

[00102] Fig. 36 illustrates a portion of a vent assembly 400 according to yet another embodiment of the invention. Vent assembly 400 includes a plurality of vent holes 405 arranged in a predetermined pattern. Fig. 37 is a plan view of the pattern which includes center rows 410 each including nine holes in side-by-side relation. Each center row 410 is flanked by an intermediate row 415, which in turn is flanked by outside rows 420. Each intermediate row 415 includes seven holes, while each outside row 420 includes three holes. The holes in outside rows 420 are aligned with holes in the center rows 410, while the holes in intermediate rows 415 are offset from both the center rows 410 and the outside rows 420. Furthermore, it should be appreciated that any of the vent configurations described above, especially the embodiments described in relation to Figs. 35-37, could be incorporated into a nasal mask (e.g., ResMed's Mirage[®] nasal mask) or a full-face (nasal-oro) mask (e.g., ResMed's Ultra-Mirage[®] full face mask).

[00103] The vent holes in any of the above embodiments may be provided directly on the frame and/or the cushion. In an alternative, the frame, cushion and/or air delivery conduit can be provided with an aperture into which a substrate with the

holes is inserted or otherwise provided. The substrate may take the form of an insert, such as disclosed in U.S. Patent No. 6,561,190, incorporated herein by reference in its entirety. In another alternative, vent holes may be provided in headgear.

[00104] As can be seen from Figs. 5, 6 and 9, the holes 130 are preferably arranged in two rows having a predetermined pitch. For example, the rows are offset to allow more holes to be fitted into a smaller space, thereby keeping the size of the vent channel 90 to a minimum. As seen in Fig. 6, the centers of holes in adjacent rows are spaced a depth DH of about .75 to 1.25 mm, preferably 1.0mm, and a width WH of about 1.1-1.3mm, preferably about 1.175mm. The center-to-center distance ("true pitch") between the holes is about 1.5-1.6mm, preferably about 1.54mm. The length LVC of the vent channel is about 45-55mm, preferably about 48mm.

[00105] Each hole 130 preferably has the following dimensions: length HL: about 1.0-2.5mm, preferably about 1.7mm; outlet diameter HO: about 0.5-1.0mm, preferably about 0.7mm; radius of curvature at the upper end of the hole (HR): about 0.15-0.35mm, preferably about 0.25mm.

2.1.3 Cushion Channels and Cut Outs

[00106] Frame 65 includes lugs 140 (Figs. 3, 4, 6, 8 and 10) to help form a longitudinal cushion channel 145 into which an edge portion 71 of the cushion 70 is fitted, to secure the cushion relative to the frame to form a frame/cushion subassembly prior to attachment of the clip. As shown in Fig.4, cushion channel 145 is provided on each side of the vent channel. Cushion channel 145 is provided with structure to enhance alignment with the cushion. For example, each cushion channel 145 may include one or more cut outs 150 to receive corresponding lugs 155 (e.g., Fig. 20) of the cushion (described below). Frame also includes circumferential channels 146 (Fig. 5) to receive end portions 72 of the cushion 70.

2.1.4 Coring

[00107] Frame includes cored portions 160 (Fig. 10) adjacent to each lateral connector. Cored portions 160 help facilitate manufacturing, by thinning out the plastic section. A thickened section has a higher possibility of leaving sink marks.

2.1.5 Noise Reduction

[00108] The vent channel 90 of the frame 65 is structured to reduce vent noise generated by the vent holes. In the illustrated embodiment, the entrance to the vent holes 130 is located at the bottom of the vent channel 90. As a result, turbulent inflow is entrained into or guided within the vent channel 90 which decreases the turbulence of the flow in the mask chamber before the flow passes into the vent holes 130. Because the flow entering the vent is not highly turbulent, the noise induced by turbulent flow passing through the vent is reduced (effecting a noise reduction throughout the whole breathing cycle, not just inhalation).

[00109] The vent channel 90 also acts as a buffer between the high flow region (generally between the opposed inlet apertures 115) and the entrance to the vent holes 130. This arrangement has the effect of quieting the nasal assembly during inhalation when flow through the nasal assembly is at its highest and most turbulent.

[00110] Specifically, inflow during inhalation includes a relatively high velocity cross flow, wherein air enters the cushion assembly 15 laterally and normal to the orientation of the vent holes 130. Noise may be produced by this air flow if it encounters obstructions or irregularities, such as an array of vent holes. By providing the vent holes 130 at the bottom of the vent channel 90, the air flow does not directly encounter this irregular geometry. Therefore, noise generated from the vent holes 130 may be eliminated and/or reduced.

2.2.0 Cushion

[00111] Cushion 70 includes a main body 170 supporting a pair of nozzle members 175 that are designed to engage with a user's nares in use.

2.2.1 Lugs

[00112] As best shown in Figs. 17 and 20, cushion includes one or more lugs 155 that are fitted snugly relative to cut 150 outs in frame 65. The provision of the matching lugs and cut outs helps prevent the assembly of cushion 70 (that has no vent holes) to a frame (not shown) without a vent. Thus, the situation is avoided where the user inadvertently attempts to couple a ventless frame with a ventless cushion.

2.2.2 No vent holes

[00113] Cushion 70 has no vent holes, since the vent holes are provided in the frame 65. However, the wall thickness of a portion 180 (Fig. 19) of the cushion remains thickened to support nozzle members 175.

2.2.3 Corner Lugs

[00114] As shown in Fig. 20, cushion 70 includes corner lugs 185 to interface with cored portions 160 of frame 15.

2.3.0 Clip

[00115] Clip 75 includes a main body having lateral ends, either one of which can be assembled to the cushion/frame subassembly, by sliding action to secure same.

2.3.1 Vent Window

[00116] Clip 75 includes a vent window 190 that aligns with the vent holes in vent channel upon assembly of the clip to the cushion/frame subassembly.

2.3.2 Ribs

[00117] Clip 75 includes ribs 195 provided on each lateral side thereof. Ribs 195 help with strength and stiffness, as well as provide a grip surface.

2.3.3 Wings

[00118] Clip 75 includes wings 200 on each side of the main body. Wings 200 preferably have a compound curved shape, to improve strength and stiffness.

3.0 Alternative Mask Arrangements

[00119] Vent configurations, such as those described above, may be incorporated into other mask arrangements. For example, Figs. 38-44 illustrate an embodiment of a frame 550 for a full-face (nasal-oro) mask. As illustrated, the frame 550 includes an upper support member 560 adapted to support a forehead support, lower headgear clip receptacles 570 adapted to be engaged with clips provided to straps of a headgear assembly, and a lower bore 580 adapted to engage an inlet conduit, e.g., elbow. Also, the perimeter of the frame includes a plurality of slots 590 therethrough, e.g., three slots. The slots 590 are adapted to engage a cushion clip that retains a cushion on the

frame 550. Such a frame arrangement is disclosed in PCT Application Nos. PCT/AU2006/000035 and PCT/AU2006/000037, each incorporated herein by reference in its entirety.

[00120] As best shown in Figs. 38, 40, 41, and 44, the upper portion of the frame 550 includes a vent assembly 500 similar to that shown in Fig. 35. The vent assembly 500 is positioned on the frame 550 below spaced-apart side walls 565 of the upper support member 560. The vent assembly 500 includes a plurality of holes 505 arranged in a three column pattern. As illustrated, the columns are aligned or parallel to the longitudinal axis L of the frame, e.g., the center column is aligned with the longitudinal axis and the outside columns are parallel to the longitudinal axis (see Fig. 41). The center column 510 includes 10-20 holes, e.g., 15 holes, and each outside column 515 includes 8-15 holes, e.g., 12 holes. The holes 505 in the outside columns 515 are aligned with the holes 505 in the center column 510, with the center column 510 having one additional hole at the upper end and two additional holes at the lower end. In the illustrated embodiment, each hole 505 has a generally part conic shape, including opposed walls that converge from a larger (inside) diameter (e.g., about 1.28 mm) to a smaller (outside) diameter (e.g., about 0.7 mm), as viewed in the direction of exhausted gas. The included angle of the cone may be about 14°, the height of the cone may be about 2.38 mm, and a radius provided on the inside diameter may be about 0.75 mm. However, the frame 550 may include other vent arrangements, e.g., the vent arrangement shown in Figs. 36-37. In this arrangement, the first and second center columns may be parallel to and offset from the longitudinal axis of the frame.

[00121] Figs. 45-52 illustrate a vent configuration incorporated into a frame 650 for a nasal and mouth mask. As illustrated, the frame 650 includes a main body 660 having a side frame portion 670 on each lateral side thereof. The main body 660 includes an aperture 662 and a flanged collar member 664 adapted to engage an elbow. Also, the frame 650 includes a channel 680 for retaining a mouth cushion which supports nasal prongs. In addition, each side frame portion 670 includes headgear attachment points, e.g., upper and lower anchors 672, 674, for attaching a headgear assembly. Such a frame arrangement is disclosed in U.S. Provisional Application No. 60/795,562, entitled "Mask System" and filed April 28, 2006, the entirety incorporated herein by reference.

[00122] In the illustrated embodiment, a vent assembly 600 is provided in each side frame portion 670 of the frame 650, adjacent the upper anchors 672. Each vent assembly 600 includes an array or pattern of relatively small holes 605 arranged in a plurality of columns, e.g., 3-10 columns, and in the example illustrated, 5 columns. The 5 columns are vertically staggered with respect to one another. Also, the first hole in each column cooperate to form an axis A that is angled at an angle α (when viewed from the front as shown in Fig. 48) of about 15-35°, e.g., 25°, with respect to vertical axis V. As best shown in the side view of Fig. 50, each hole is provided along a plane P (approximate plane shown in Fig. 50 due to frame angle in side view) that forms an angle β of about 20-40°, e.g., 30°, with respect to vertical axis V. As shown in the bottom view of Fig. 51, each hole has a longitudinal axis L that is angled at an angle of about -10° to about 45°, e.g., 0°, with respect to transverse axis T. Each column includes 2-6 holes, e.g., 4 holes. In the illustrated embodiment, each hole 605 has a generally part conic shape, including opposed walls that converge from a larger diameter to a smaller diameter, as viewed in the direction of exhausted gas. The smaller diameter may be about 0.7 mm, the larger diameter may be about 1 mm, the included angle of the cone may be about 10°, and the height of the cone may be about 1.7 mm. However, other vent arrangements are possible.

[00123] As illustrated, the holes 605 are located away from the elbow aperture 662 to avoid air flow interference. Also, the holes 605 are located near headgear attachment points 672 where the frame 650 is relatively flat to the users face for the anchor structures. In addition, the holes 605 are positioned on relatively flat portions of the frame 650 so that air may be vented perpendicularly from the general plane of the patient's face to avoid air jetting towards a bed partner. Thus, this vent arrangement optimizes mask operation and is synergistic in that it utilizes an area of the frame 650 which is relatively flat to the patient's face for two purposes, i.e., anchor structure and perpendicular venting. Aesthetics of the frame 650 are also improved significantly by reducing the number of relatively flat areas that are provided on the frame 650.

4.0 Alternative Embodiment of Cushion Assembly

[00124] Figs. 53-66 illustrate a cushion assembly 715 according to another embodiment of the present invention. As illustrated, the cushion assembly 715 includes a frame 765 and a cushion 770 provided to the frame 765. Although not

illustrated, it should be understood that a clip, e.g., clip 75 described above, may be provided to secure the cushion 770 to the frame 765. Figs. 53-55 show assembled views of the cushion 770 and frame 765, Figs. 56A-61 show the frame 765 in isolation, Figs. 62-64 show the assembly of the frame 765 and the cushion 770, and Figs. 65-66 illustrate orientation of the cushion assembly 715.

4.1.0 Frame

[00125] As best shown in Figs. 56A-61, the frame 765 has a main body 780 and lateral sides. Each lateral side includes a lateral connector portion 785. The frame 765 is preferably made of molded plastic, e.g., polycarbonate and/or polypropylene.

4.1.1 Vent Channel

[00126] The main body 780 of the frame 765 is provided with a vent channel 790 defined by a base wall 792 and a pair of side walls 794. The vent channel 790 extends from an inside surface 795 of the main body toward the base wall 792.

4.1.2 Vent Holes

[00127] The channel 790 is in communication with a plurality of vent holes 830, e.g., 6-60 vent holes, and preferably about 35-45 vent holes, although there could be more than 60 holes or less than 6 holes, depending on application. In the example of Fig. 57, there are 38 holes. Each vent hole 830 may have a similar conic shape such as vent hole 130 described above. In addition, the vent arrangement includes offset rows of vent holes. However, other arrangements are possible.

4.1.3 Cushion Channels and Cut Outs

[00128] The frame 765 includes lugs 840 to help form a longitudinal cushion channel 845 into which an edge portion 771 of the cushion 770 is fitted, to secure the cushion 770 relative to the frame 765 to form a frame/cushion subassembly prior to attachment of the clip. The cushion channel 845 is provided on each side of the vent channel 790 and includes one or more cut outs 850 to receive corresponding lugs of the cushion 770 (as described above with respect to cushion 70 and frame 65). Frame 765 also includes circumferential channels 846 to receive end portions of the cushion 770.

4.1.4 Thickened Side Wall

[00129] In the illustrated embodiment, the side walls 794 of the frame 765 are locally thickened at the cut outs 850. Specifically, the wall sections S1 at the cut outs 850 (i.e., between lugs 840) are thickened with respect to the adjacent wall sections S2 supporting lugs 840. This arrangement increases the strength of the side wall 794 to reduce bending stress, which results in an increase in strength of the overall frame 765.

[00130] For example, the wall section S1 between lugs 840 shown in Figs. 58-59 is thicker than the wall section S2 supporting lugs 840 shown in Figs. 60-61. In an embodiment, the wall section S1 may have a thickness T of about 1.20 mm and the wall section S2 may have a thickness t of about 1.0 mm. However, other thicknesses are possible depending on application. In previous designs, the side walls 794 had a substantially constant wall thickness along its length.

4.1.5 Fillet Size Increase

[00131] As shown in Figs. 56A, 56B, and 57, the size of the fillets F between the side walls 794 and the lugs 840 has been increased relative to previous designs. In an embodiment of the fillet F , as shown in Fig. 56B, the radius R_1 may be in the range of 0.1 – 0.95 mm, e.g., preferably 0.6 mm, the radius R_2 may be in the range of 0.1 – 0.95 mm, e.g., preferably 0.5 mm, and the radius R_3 may be in the range of 0.1 – 1.2 mm, e.g., preferably 1.2 mm. Although specific dimensions and ranges of the fillet F are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

[00132] The fillet size increase provides better stress distribution at the junction between the side walls 794 and the lugs 840. Thus, the fillet size increase (along with the thickened side walls described above) results in overall strength improvement of the frame 765.

4.2.0 Cushion

[00133] The cushion 770 is substantially similar to the cushion 70 described above. As illustrated, the cushion 770 includes a main body 870 supporting a pair of nozzle members 875 that are designed to engage with a user's nares in use.

4.2.1 Logo/Indicators

[00134] The main body 870 of the cushion 770 includes a size indicator 702, e.g., medium (M) size, and a series of position arrows 704 to facilitate positioning between the headgear and the cushion assembly 715. In addition, the cushion 770 includes text and/or a logo 706, e.g., ResMed logo. As illustrated, the logo 706, the size indicator 702, and the position arrows 704 protrude from the main body 870, e.g., raised configuration, to facilitate recognition.

[00135] In the illustrated embodiment, the logo 706, the size indicator 702, and the position arrows 704 are provided on one side of the main body 870. This labeling arrangement provides a visual cue to assist the patient in achieving correct alignment and orientation of the cushion 770 and frame 765 with respect to the patient.

[00136] Specifically, the labeling arrangement prevents incorrect assembly of the cushion assembly 715 (i.e., cushion 770 and frame 765) onto the headgear. As shown in Fig. 65, when the cushion assembly 715 is correctly oriented on the headgear (and hence correctly oriented with respect to the patient in use), the logo 706, size indicator 702, and position arrows (not visible in Fig. 65) face outwards or away from the patient in use. However, as shown in Fig. 66, when the cushion assembly 715 is incorrectly oriented on the headgear (and hence incorrectly oriented with respect to the patient in use), the logo 706, size indicator 702, and position arrows (not visible in Fig. 66) face inwards or towards the patient. Thus, the patient may easily determine if the cushion assembly 715 is correctly oriented.

[00137] Often, the frame 765 remains attached to the headgear and the cushion 770 is removed from the frame/headgear subassembly, e.g., for cleaning. When the cushion 770 is re-assembled to the frame 765 (e.g., see Figs. 62-64), the logo 706, size indicator 702, and position arrows 704 may be used as a visual cue to assist the patient in achieving correct alignment and orientation of the cushion 770 onto the frame 765.

[00138] In an embodiment, the logo 706, the size indicator 702, and/or the position arrows 704 may be provided to facilitate orientation.

5.0 Alternative Embodiment of Nasal Assembly

[00139] Figs. 67-83 illustrate a nasal assembly 905 according to another embodiment of the present invention. As shown in Fig. 67, the nasal assembly 905

includes a cushion assembly 915, yokes 925 to provide stability to the sides of the headgear, seal portion 950 and elbow 935 provided to one end of the cushion assembly 915, and seal portion 950 and plug 930 provided to the other end of the cushion assembly 915. The positions of the swivel elbow 935 and the plug 930 may be interchanged, according to preference, e.g., the typical sleeping position of the patient.

[00140] The yoke 925 may include a yoke ring 955. The cushion assembly 915 may be adjustably rotated with respect to headgear, to a position which best fits the patient. The ring 955 of the yoke 925 associated with the other side of the headgear may include one or more alignment markers 961 that can be selectively aligned with one of a plurality of alignment markers 960 provided on the cushion.

5.1 Swivel Elbow

[00141] The swivel elbow 935 includes one end provided to the cushion assembly 915 and the opposite end provided to an air delivery tube. As illustrated, the end provided to the cushion assembly 915 includes two prongs 937 and a pair of key-shaped apertures 939 (only one aperture being visible) to reduce stress. Such a swivel elbow is disclosed in PCT Application No. PCT/AU2004/000207, filed February 20, 2004, the entirety of which is incorporated herein by reference.

5.2 Cushion Assembly

[00142] The cushion assembly 915 includes a frame 965, a cushion 970 and a clip 975. Figs. 68-75 show the assembly of the frame, cushion, and clip, and Figs. 76-83 show the clip in isolation.

5.3 Frame

[00143] The frame 965 may be similar to one or more of the frames described above. Therefore, the frame 965 will not be described in further detail.

5.4 Cushion

[00144] The cushion 970 may be similar to one or more of the cushions described above. Therefore, the cushion 970 will not be described in further detail.

5.5 Clip

[00145] The clip 975 includes a main body having lateral ends, either one of which can be assembled to the cushion/frame subassembly, by sliding action to secure the same. Such a clip is disclosed in U.S. Design Application No. 29/258,084, filed April 14, 2006, the entirety of which is incorporated herein by reference.

5.5.1 Vent Window

[00146] The clip 975 includes a vent window 1090 that aligns with the vent holes in vent channel upon assembly of the clip to the cushion/frame subassembly.

5.5.2 Ribs

[00147] The clip 975 includes two ribs 1095, 1097 provided on each lateral side thereof. The two ribs 1095, 1097 increases stiffness to prevent disassembly of the clip 975, thus improving the retention and seal of the cushion 970 to the frame 965. In addition, the two ribs 1095, 1097 improve usability by providing grip during assembly/disassembly.

5.5.3 Wings

[00148] The clip 975 includes wings 1000 on each side of the main body. The wings 1000 extend laterally from a bottom of the clip 975 (e.g., in contrast to wings 200 that extend from a top surface of clip 75).

[00149] In addition, each wing 1000 has a reinforced section 1002 that increases stiffness in the clamping direction to prevent disassembly of the clip 975, thus improving the retention and seal of the cushion 970 to the frame 965.

6.0 Alternative Vent Arrangement

[00150] Fig. 84 illustrates a nasal and mouth mask 1115 including a frame 1150 having a vent assembly 1100 according to another embodiment of the present invention. The frame 1150 is substantially similar to the frame 650 described above. As illustrated, the frame 1150 includes a main body 1160 having a side frame portion 1170 on each lateral side thereof. The main body 1160 includes an aperture 1162 (e.g., see Fig. 85) adapted to retain an elbow 1135. Also, the frame 1150 is structured to retain a mouth cushion which supports nasal prongs 1175. In addition, each side

frame portion 1170 includes headgear attachment points, e.g., upper and lower anchors 1172, 1174, for attaching a headgear assembly.

[00151] In contrast to the frame 650, the frame 1150 includes a vent assembly 1100 that extends around the aperture 1162 and hence the elbow 1135 in use. As schematically shown in Fig. 85, the frame 1150 includes a relatively flattened area 1151 around the aperture 1162 (also referred to as an elbow mounting hole) adapted to retain the elbow 1135. The vent assembly 1100 is provided to the relatively flattened area 1151 and includes an array or pattern of relatively small holes 1105 arranged in concentric circles around the aperture 1162. This arrangement directs air directly away from all materials, e.g., pillows and bed linens, to reduce noise, and spreads the holes over a relatively wide area so that the bed partner will not be affected by a concentrated airstream.

[00152] In the illustrated embodiment, the holes 1105 are arranged in two concentric circles C1, C2 around the aperture 1162. However, the holes may be arranged in any number of circles around the aperture, e.g., 1-10 concentric circles. Also, each circle may include any suitable number of holes, e.g., 5-50 holes. The holes in adjacent circles may be aligned and/or offset from one another. However, the holes 1105 may be arranged in other suitable arrangements around the aperture 1162. For example, the holes 1105 may be non-concentrically arranged around the aperture 1162, e.g., randomly arranged. In addition, each hole 1105 may include a generally part conic shape as described above.

[00153] It should be appreciated that the vent assembly 1100 may be incorporated into other mask arrangements, e.g., nasal mask, full-face mask, etc.

6.1 Noise Reduction

[00154] The vent assembly 1100 described above may create noise when flow from the vent holes 1105 engages or blows into the back of the elbow 1135. To prevent this, a "keyed" elbow retaining clip may be used that is structured to mask holes when they are aligned with the elbow 1135.

[00155] Figs. 86-88 illustrate an elbow assembly according to an embodiment of the present invention. The elbow assembly includes an elbow 1135 (Figs. 86-87) and an elbow retaining clip 1136 (Fig. 88) to retain the elbow 1135 to the frame 1150.

[00156] The elbow 1135 includes a mating portion 1141 that is inserted into the aperture 1162 provided in the frame 1150, and the elbow retaining clip 1136 is

attached to the mating portion 1141 from an inner side of the frame 1150 so as to prevent withdrawal of the mating portion 1141 and hence the elbow 1135 from the aperture 1162.

[00157] As illustrated, the mating portion 1141 includes a key or protrusion 1143 that is adapted to engage within a corresponding keyway or recess 1137 provided to the elbow retaining clip 1136. The engagement between the key 1143 and keyway 1137 ensures that the elbow retaining clip 1136 is correctly oriented with respect to the elbow 1135.

[00158] Moreover, the elbow retaining clip 1136 includes a wiper member or tab 1139 that is structured to block, cover, and/or mask one or more vent holes 1105 from the inner side of the frame 1150 which are aligned with the elbow 1135. This arrangement blocks vent flow from blowing into the back of the elbow 1135, which reduces noise in use. Because the elbow retaining clip 1136 is keyed with the elbow 1135, the wiper member 1139 will rotate along the elbow 1135 to block the affected vent holes, i.e. vent holes aligned with the elbow 1135.

[00159] This vent and elbow arrangement has several advantages. For example, the relatively small vent holes provides lower mask noise for the patient and bed partner, and the diffuse placement of the vent holes provides a lower risk of the bed partner being affected. Because there are less complaints from the bed partner, the mask provides greater compliance as the patient may be more willing to wear the mask.

[00160] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the

above teachings. Moreover, the above teachings have applicability with patients and non-patients alike.

WHAT IS CLAIMED IS:

1. A nasal assembly for delivering breathable gas to a patient, comprising:
 - a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and
 - a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein:
 - the frame includes a vent channel provided in the main body, the vent channel including a pair of side walls extending from the main body towards a base wall, said base wall including at least one vent hole.
2. The nasal assembly according to claim 1, wherein the side walls converge towards the base wall at a predetermined angle.
3. The nasal assembly according to claim 2, wherein the predetermined angle is in the range of 2-5 degrees.
4. The nasal assembly according to any one of claims 2-3, wherein the predetermined angle is about 2 degrees.
5. The nasal assembly according to any one of claims 1-4, wherein the width between the side walls is about 2-3 mm, as measured at the base wall.
6. The nasal assembly according to claim 5, wherein the width is about 2.6 mm.
7. The nasal assembly according to any one of claims 1-6, wherein the lateral connectors define a main passage for incoming pressurized gas, said vent channel being offset the main passage.
8. The nasal assembly according to any one of claims 1-7, wherein the cushion has no vent holes.

9. The nasal assembly according to any one of claims 1-8, wherein each side wall of the vent channel has a first end adjacent the base wall having a first radius of curvature of about 0.2-0.4 mm, and a second end opposite the first end having a second radius of curvature of about 0.5-1.5mm.

10. The nasal assembly according to claim 9, wherein the first radius of curvature is about 0.3 mm and the second radius of curvature is about 0.9-1.0mm.

11. The nasal assembly according to any one of claims 1-10, wherein the vent channel has a length of about 45-50 mm.

12. The nasal assembly according to claim 11, wherein the length is about 48 mm.

13. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and

a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein:

the frame includes a plurality of vent holes, said vent holes being provided in two or more rows arranged such that the vent holes are offset from one another.

14. The nasal assembly according to claim 13, wherein each row includes over 10 vent holes.

15. The nasal assembly according to any one of claims 13-14, wherein there are two rows and a total of 35-45 vent holes.

16. The nasal assembly according to any one of claims 13-15, wherein holes of adjacent rows are positioned along a predetermined pitch.

17. The nasal assembly according to any one of claims 13-16, wherein a center of a first said hole in one row is circumferentially spaced from a center of another said hole in the adjacent row to a depth of about 1.0mm.

18. The nasal assembly according to any one of claims 13-17, wherein a center of a first said hole in one row is longitudinally spaced from a center of another said hole in the adjacent row a width of about 1.175mm.

19. The nasal assembly according to any one of claims 13-18, wherein each said hole has a length of about 1.7mm.

20. The nasal assembly according to any one of claims 13-19, wherein each said hole has an outlet side having a diameter of about 0.7mm.

21. The nasal assembly according to any one of claims 13-20, wherein each said hole has side walls having a radius of curvature of about 0.25mm.

22. The nasal assembly according to any one of claims 13-21, wherein said side walls converge towards the outlet side at an angle of about 5 degrees.

23. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and

a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein:

the frame includes longitudinal cushion channels to receive longitudinal edges of the cushion, at least one of said cushion channels including at least one cut out to receive a lug of the cushion upon assembly.

24. The nasal assembly according to claim 23, wherein each said longitudinal cushion channel includes three said cut outs and said cushion includes a corresponding number of said lugs.

25. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector; and

a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame, wherein:

the frame includes a circumferential cushion channel provided to each said lateral side of the frame, said frame including a cored portion generally aligned with each circumferential cushion channel, said cushion including a corner lug to interface with each said cored portion.

26. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and lateral sides, each lateral side including an integrally formed lateral connector, the frame including at least one vent hole;

a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame; and

a clip to secure the cushion to the frame, wherein:

the clip includes a vent window generally aligned with the at least one vent hole.

27. The nasal assembly according to claim 26, wherein the clip includes a rib provided to each lateral end thereof, on each side of the vent window.

28. The nasal assembly according to claim 27, wherein the clip includes two ribs provided to each lateral end thereof.

29. The nasal assembly according to any one of claims 26-28, wherein the clip includes a wing portion provided to the top and bottom portions of the clip.

30. The nasal assembly according to claim 29, wherein each wing portion has a compound curve.

31. The nasal assembly according to claim 29, wherein each wing portion extends laterally from a bottom of the clip.

32. The nasal assembly according to claim 31, wherein each wing portion has a reinforced section that increases stiffness.

33. The nasal assembly according to any one of claims 1-32, wherein the frame may be rotated with respect to the pair of second connector portions so as to adjust a position of the nozzles with respect to the patient's nose in use, without detaching the first and second connector portions.

34. The nasal assembly according to any one of claims 1-33, further comprising a seal portion provided to each lateral connector of the frame, the seal portion having an outer surface supporting a portion of a headgear assembly and an aperture to support either an elbow or plug.

35. The nasal assembly according to claim 34, wherein each seal portion includes a groove that is engagable a ringed yoke of the headgear assembly.

36. A patient interface for delivering breathable gas to a patient, comprising:

a frame;

a cushion to communicate with a patient's airways in use, the cushion being coupled with the frame; and

a vent portion including a plurality of vent holes, said vent holes being provided in two or more rows and the rows being arranged such that the vent holes are offset from one another.

37. The patient interface according to claim 36, wherein the vent holes are provided directly in the frame.

38. The patient interface according to claim 36, wherein the vent holes are provided on a substrate provided to the frame and/or cushion.

39. The patient interface according to at least one of claims 36-38, wherein each row includes more than 5 vent holes.

40. The patient interface according to claim 39, wherein each said row includes more than 10 vent holes.

41. The patient interface according to at least one of claims 36-40, wherein there are two rows and a total of 35-45 said vent holes.

42. The patient interface according to at least one of claims 36-40, wherein there are two rows and a total of 16-45 said vent holes.

43. The patient interface according to at least one of claims 36-40, wherein there are three rows each having more than 12 vent holes and a total of more than 35 said vent holes.

44. The patient interface according to at least one of claims 36-40, wherein there are four rows, each of which has at least three of said vent holes.

45. The patient interface according to claim 44, wherein at least two of said rows has at least seven of said vent holes.

46. The patient interface according to at least one of claims 36-45, wherein each said hole has a length of about 1.7mm.

47. The patient interface according to at least one of claims 36-46, wherein each said hole has an outlet side having a diameter of about 0.7mm.

48. The patient interface according to claim 47, wherein said holes converge towards the outlet side.

49. The patient interface according to at least one of claims 36-48, wherein said cushion is a nasal only mask.

50. The patient interface according to at least one of claims 36-48, wherein said cushion is a nasal-oro mask.

51. The patient interface according to at least one of claims 36-48, wherein said cushion comprises a pair of nozzles to sealingly engage the nares of the patient in use.

52. A full-face mask frame comprising:
a main body having a longitudinal axis; and
a vent assembly provided to the main body, the vent assembly including a plurality of holes arranged in at least one column,
wherein the at least one column is aligned with or parallel to the longitudinal axis.

53. The full-face mask frame according to claim 52, wherein the vent assembly includes a center column aligned with the longitudinal axis.

54. The full-face mask frame according to claim 53, wherein the vent assembly includes a supplemental column on each side of the center column, each supplemental column having holes that are aligned with the holes in the center column.

55. The full-face mask frame according to claim 54, wherein the center column has at least one additional hole at an upper end and/or a lower end with respect to the supplemental columns.

56. The full-face mask frame according to claim 55, wherein the center column has one additional hole at the upper end and two additional holes at the lower end.

57. The full-face mask frame according to any one of claims 54-56, wherein the center column has 10-20 holes and the supplemental columns each have 8-15 holes.

58. The full-face mask frame according to claim 57, wherein the center column has 15 holes and the supplemental columns each have 12 holes.

59. The full-face mask frame according to claim 52, wherein the vent assembly includes first and second center columns that are parallel to and offset from the longitudinal axis.

60. The full-face mask frame according to claim 59, wherein the vent assembly includes at least one supplemental column on respective sides of the first and second center columns.

61. The full-face mask frame according to claim 60, wherein each supplemental column has holes that are offset from the holes in the center columns.

62. The full-face mask frame according to any one of claims 52-61, further comprising an upper support member adapted to support a forehead support.

63. The full-face mask frame according to claim 62, wherein the vent assembly is positioned below spaced-apart side walls of the upper support member.

64. The full-face mask frame according to any one of claims 52-63, further comprising lower headgear clip receptacles adapted to be engaged with clips provided to straps of a headgear assembly.

65. The full-face mask frame according to any one of claims 52-64, further comprising a plurality of slots adapted to engage a cushion clip that retains a cushion on the frame.

66. The full-face mask frame according to any one of claims 52-65, wherein each hole has a generally part conic shape including opposed walls that converge from a larger diameter to a smaller diameter, as viewed in the direction of exhausted gas.

67. A mask frame comprising:
a main body; and
a side frame portion provided on each lateral side of the main body;
and
a vent assembly provided to each side frame portion, each vent assembly including a plurality of holes arranged in a multi-column pattern and each column being vertically staggered with respect to one another.
68. The mask frame according to claim 67, wherein each side frame portion includes upper and lower anchors adapted to attach a headgear assembly.
69. The mask frame according to claim 68, wherein each vent assembly is positioned adjacent the upper anchor.
70. The mask frame according to any one of claims 67-69, wherein each vent assembly includes a plurality of holes arranged in 3-10 columns.
71. The mask frame according to claim 70, wherein each vent assembly includes a plurality of holes arranged in 5 columns.
72. The mask frame according to any one of claims 67-71, wherein each column includes 2-6 holes.
73. The mask frame according to claim 72, wherein each column includes 4 holes.
74. The mask frame according to any one of claims 67-73, wherein each hole has a generally part conic shape including opposed walls that converge from a larger diameter to a smaller diameter, as viewed in the direction of exhausted gas.
75. The mask frame according to any one of claims 67-74, wherein the holes are positioned on relatively flat portions of the side frame portion.

76. The mask frame according to any one of claims 67-75, wherein a first hole in each column cooperate to form an axis that is angled with respect to a vertical axis of the frame.

77. The mask frame according to claim 76, wherein the axis is angled about 15-35° with respect to the vertical axis.

78. The mask frame according to any one of claims 67-77, wherein each hole is provided along a plane that forms an angle with respect to a vertical axis of the frame.

79. The mask frame according to claim 78, wherein the plane is angled about 20-40° with respect to the vertical axis.

80. The mask frame according to any one of claims 67-79, wherein each hole has a longitudinal axis that is angled with respect to a transverse axis of the frame.

81. The mask frame according to claim 80, wherein the longitudinal axis is angled about -10° to about 45° with respect to the transverse axis.

82. A mask assembly for delivering breathable gas to a patient including a mask frame according to any one of claims 52-81.

83. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame; and

a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the frame, wherein the cushion includes a size indicator, a series of position arrows, text, and/or a logo provided to one side of the cushion, the size indicator, series of position arrows, text, and/or logo adapted to provide a visual cue to assist the patient in achieving correct alignment and orientation of the cushion and frame with respect to the patient in use.

84. The nasal assembly according to claim 83, wherein the size indicator, position arrows, text, and/or logo protrude from the main body.

85. The nasal assembly according to any one of claims 83-84, wherein the size indicator, position arrows, text, and/or logo are adapted to face outwards or away from the patient when the cushion and frame is correctly oriented with respect to the patient in use.

86. A nasal assembly for delivering breathable gas to a patient, comprising:
a frame including a main body; and
a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled with the main body of the frame,
the frame includes a vent channel provided in the main body, the vent channel including a pair of side walls extending from the main body towards a base wall,
wherein each of the side walls includes a variable wall thickness along its length.

87. The nasal assembly according to claim 86, wherein the frame includes lugs that form a longitudinal cushion channel to secure the cushion, the cushion channel being provided on each side of the vent channel and including one or more cut outs between lugs.

88. The nasal assembly according to claim 87, wherein the side walls of the frame are locally thickened at the cut outs.

89. The nasal assembly according to claim 88, wherein wall sections of the side walls at the cut outs are thickened with respect to adjacent wall sections of the side walls that support lugs.

90. The nasal assembly according to claim 89, wherein the wall sections at the cut outs have a thickness of about 1.20 mm, and the wall sections that support lugs have a thickness of about 1.0 mm.

91. The nasal assembly according to claim 87, wherein the frame includes a fillet between each side wall and lug, each fillet having a first radius in the range of 0.1 – 0.95 mm, a second radius in the range of 0.1 – 0.95 mm, and a third radius in the range of 0.1 – 1.2 mm.

92. The nasal assembly according to claim 91, wherein the first radius is about 0.6 mm, the second radius is about 0.5 mm, and the third radius is about 1.2 mm.

93. The nasal assembly according to any one of claims 86-92, wherein the base wall includes at least one vent hole.

94. A nasal assembly for delivering breathable gas to a patient, comprising:
a frame; and
a cushion including a pair of nozzles to communicate with nasal passages of a patient's nose in use, the cushion being coupled to the frame,
wherein the frame includes a vent channel that leads to at least one vent hole, the vent channel adapted to buffer and/or separate higher velocity and more turbulent air flow into and around the frame from an entrance to the at least one vent hole.

95. The nasal assembly according to claim 94, wherein the vent channel includes a pair of side walls extending towards a base wall, said base wall including the at least one vent hole.

96. A mask frame comprising:
a main body including an aperture adapted to communicate with an elbow; and
a vent assembly provided to the main body, the vent assembly including a plurality of holes arranged around the aperture.

97. The mask frame according to claim 96, wherein the holes are arranged in one or more concentric circles around the aperture.

98. The mask frame according to claim 97, wherein the holes are arranged in two concentric circles around the aperture.

99. The mask frame according to any one of claims 97-98, wherein each circle includes 5-50 holes.

100. The mask frame according to any one of claims 97-99, wherein holes in adjacent circles are aligned and/or offset from one another.

101. A mask assembly for delivering breathable gas to a patient, comprising:

a mask frame according to any one of claims 96-100; and
an elbow provided to the mask frame.

102. The mask assembly according to claim 101, wherein the elbow is retained to the mask frame by an elbow retaining clip.

103. The mask assembly according to claim 102, wherein the elbow includes a mating portion that is inserted into the aperture provided in the frame, and the elbow retaining clip is attached to the mating portion from an inner side of the frame.

104. The mask assembly according to claim 103, wherein the mating portion of the elbow includes a key that is adapted to engage within a corresponding keyway provided to the elbow retaining clip.

105. The mask assembly according to any one of claims 102-104, wherein the elbow retaining clip includes a wiper member that is structured to block, cover, and/or mask one or more vent holes from an inner side of the frame which are aligned with the elbow.

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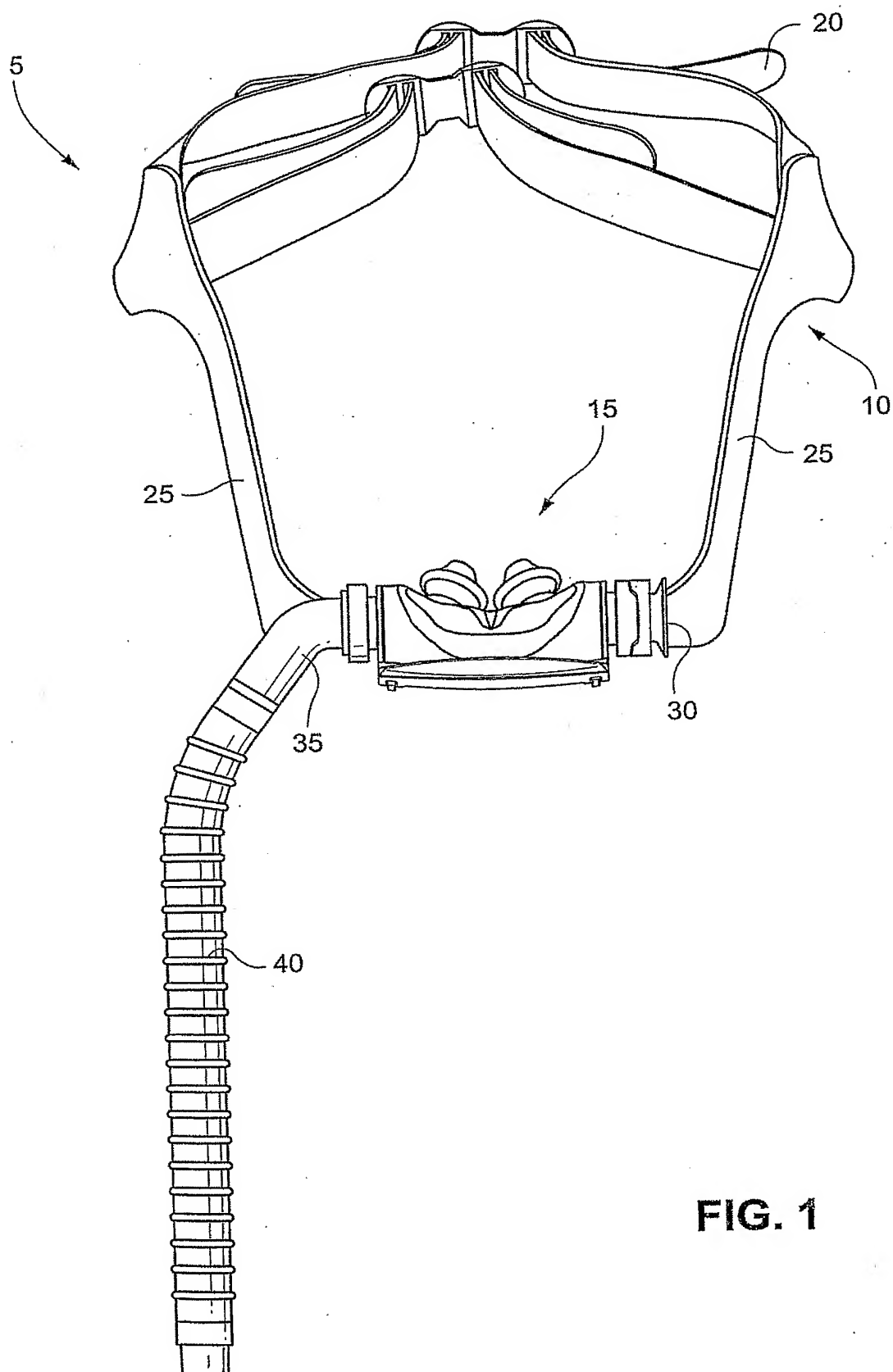
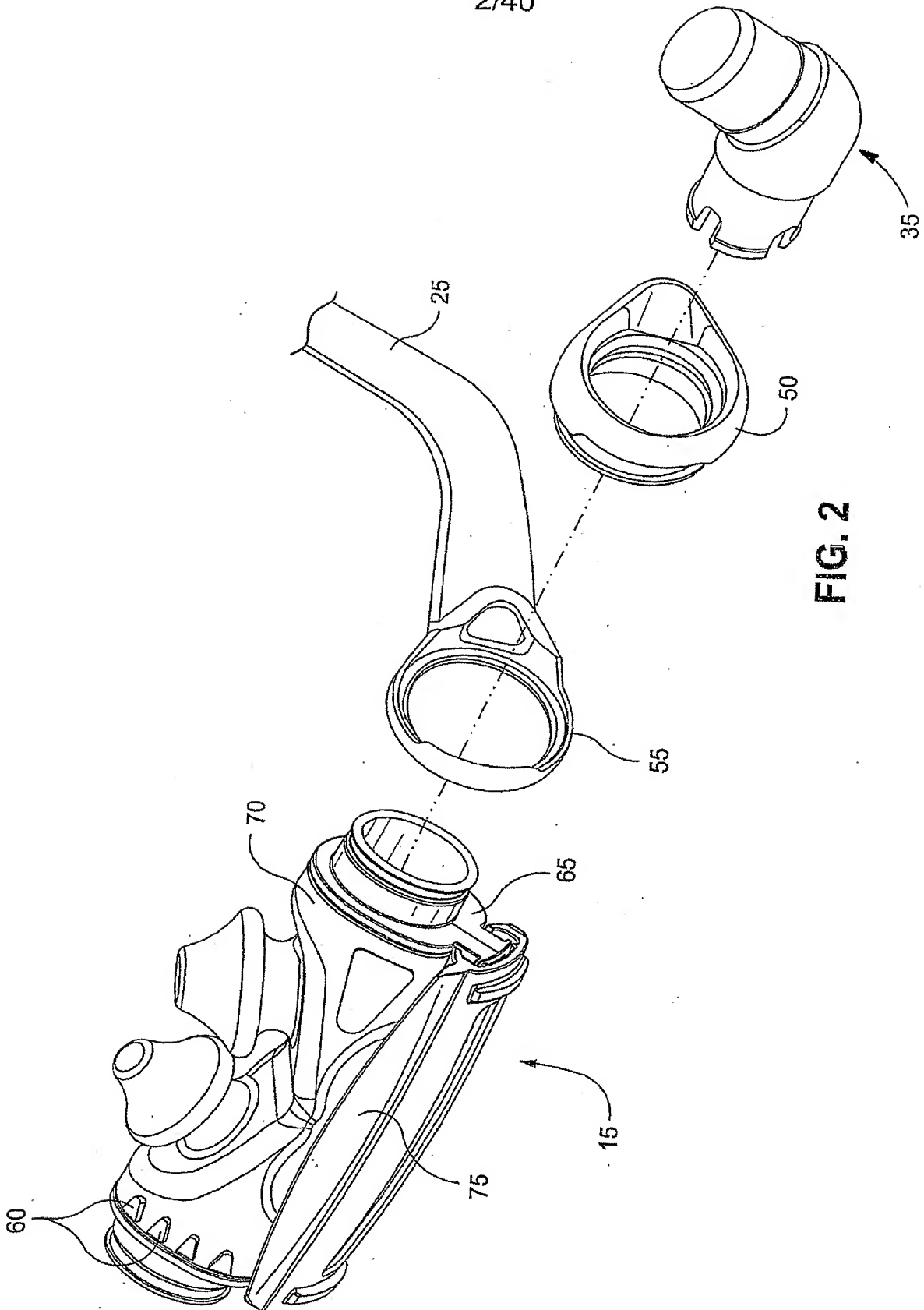


FIG. 1

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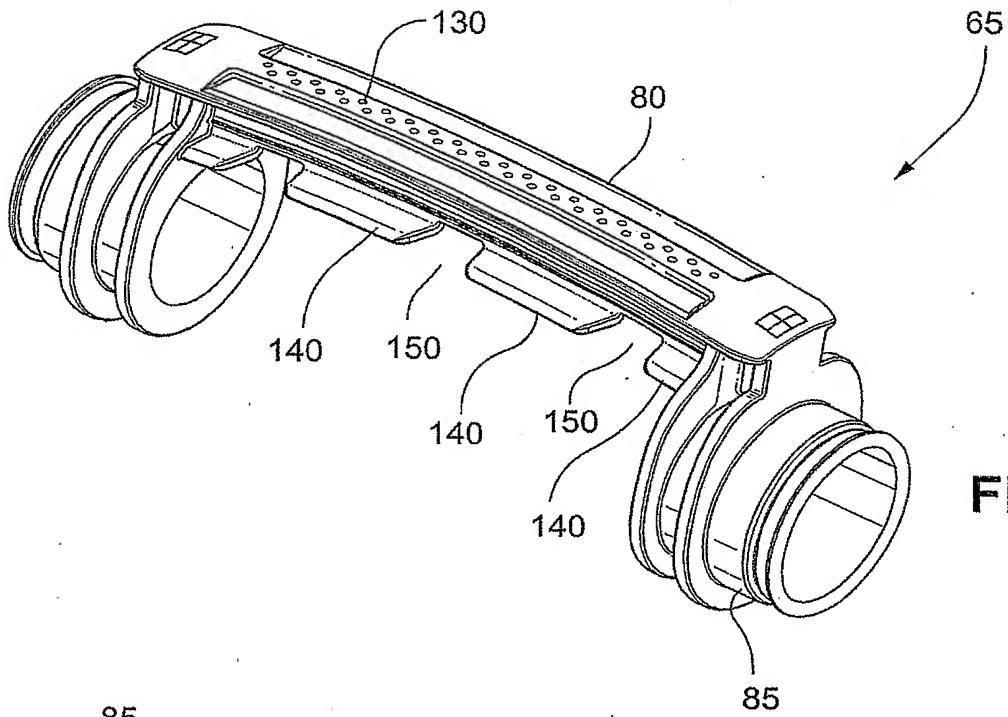


FIG. 3

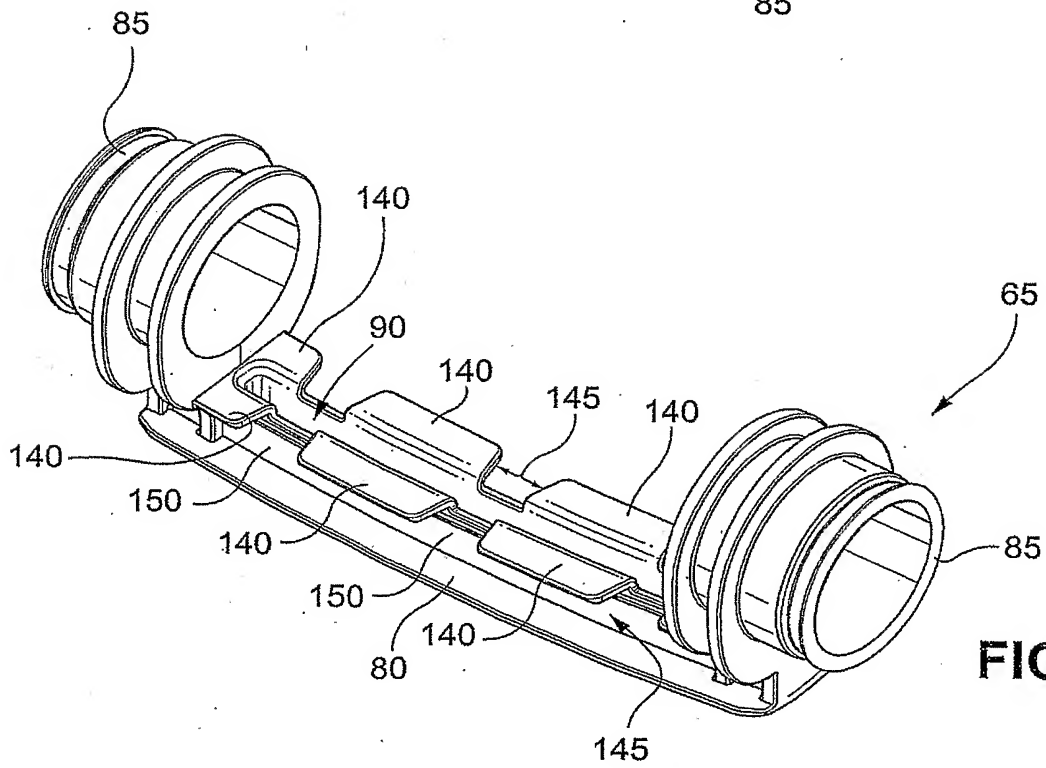


FIG. 4

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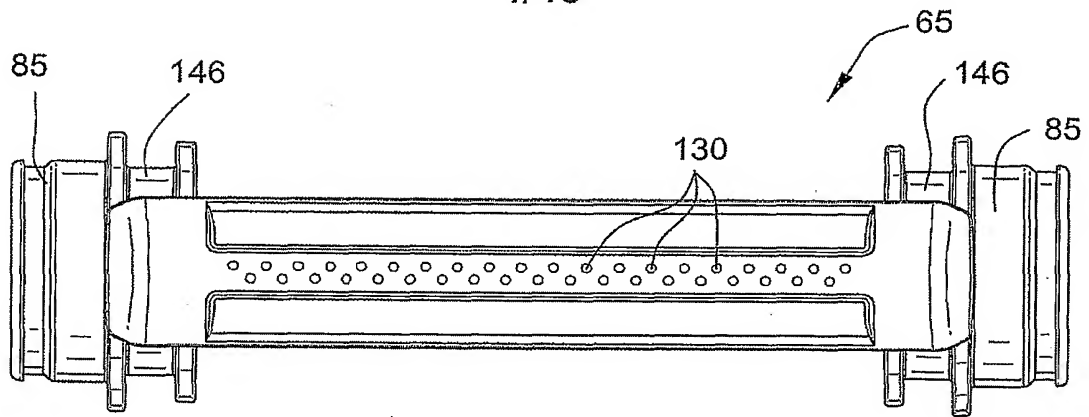


FIG. 5

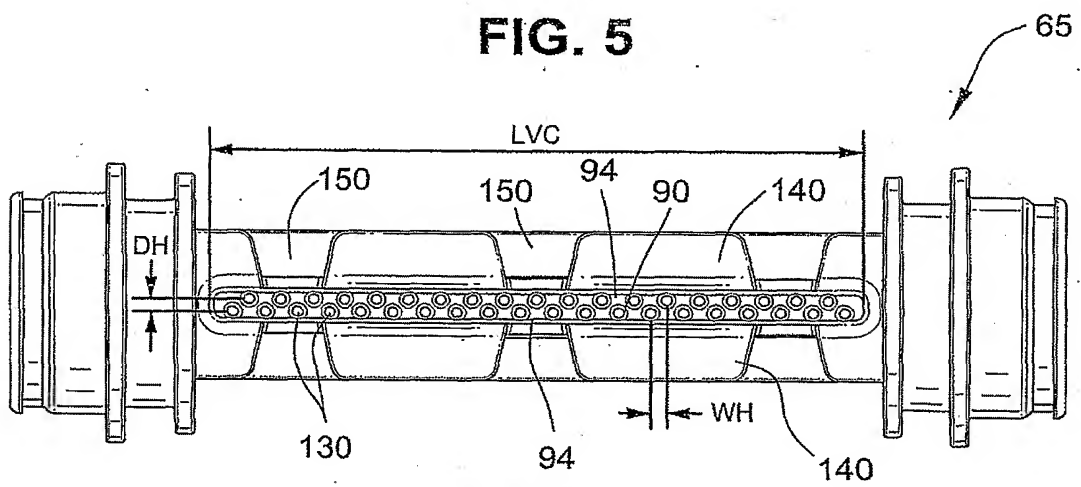


FIG. 6

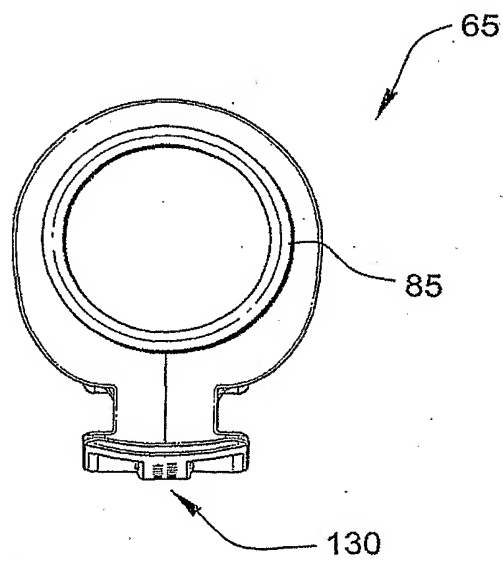
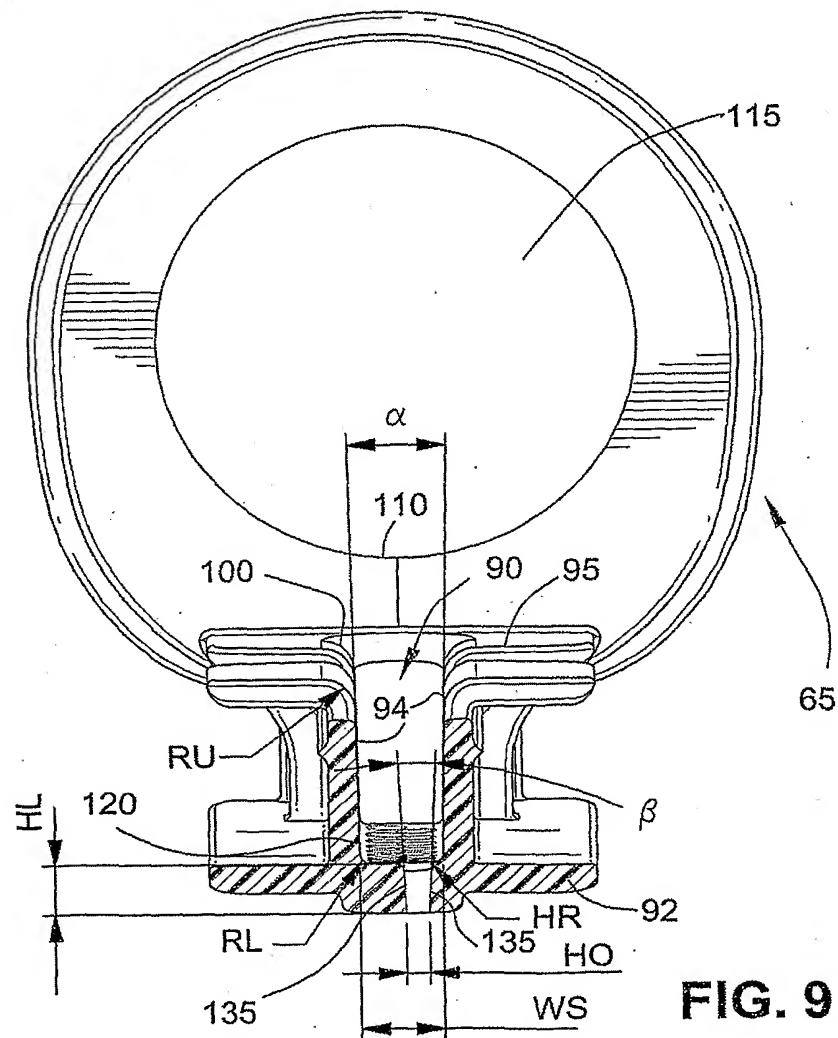
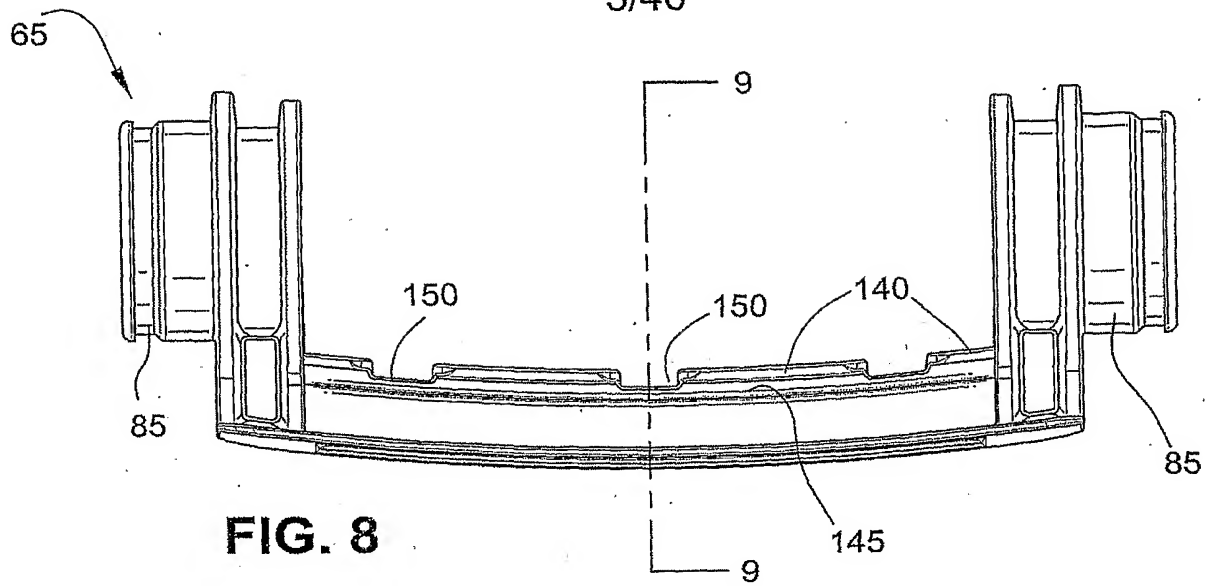
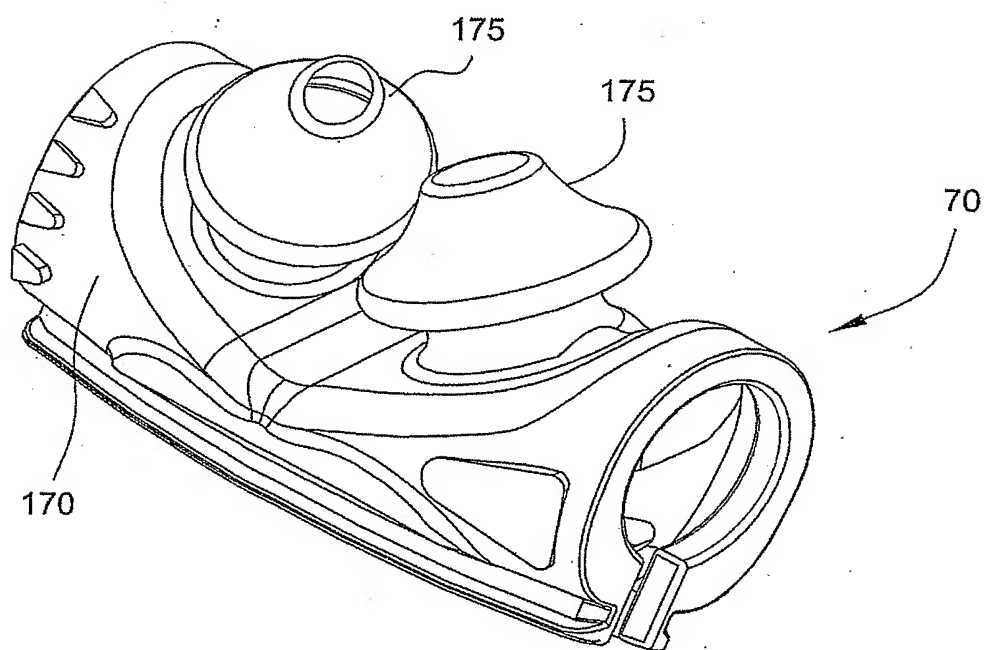
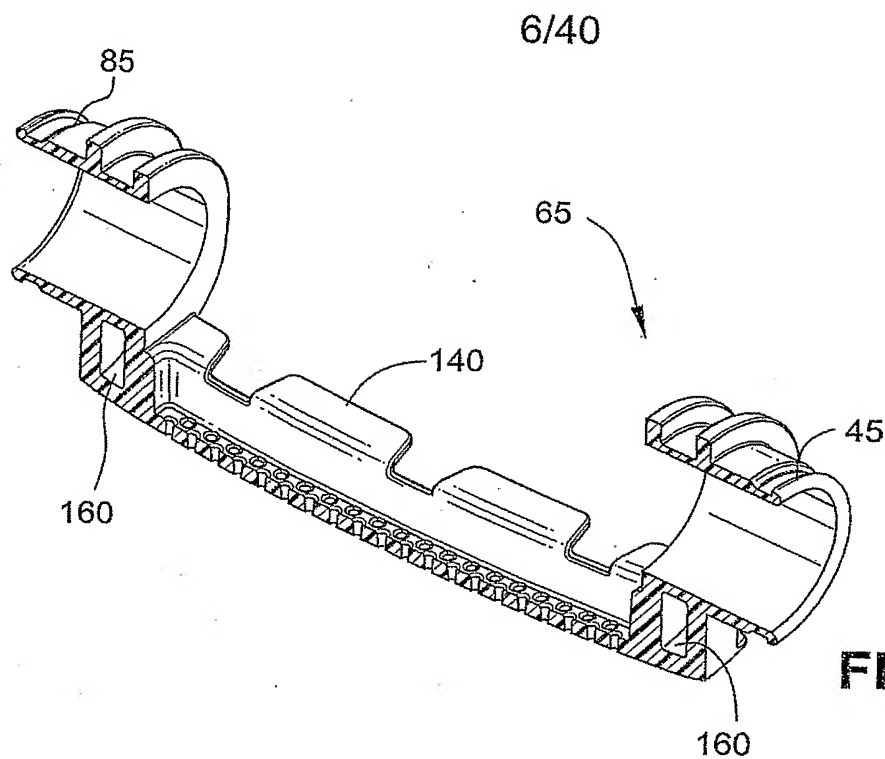


FIG. 7

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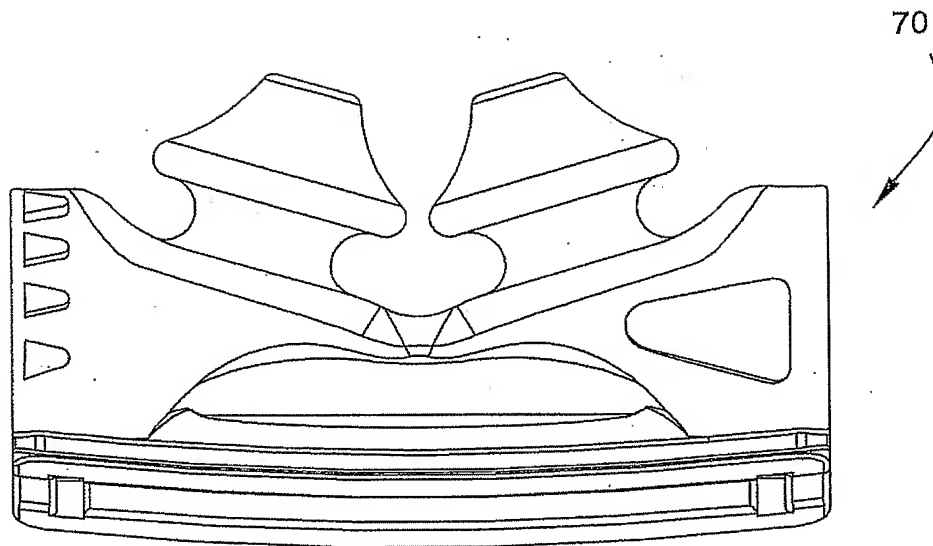


FIG. 12

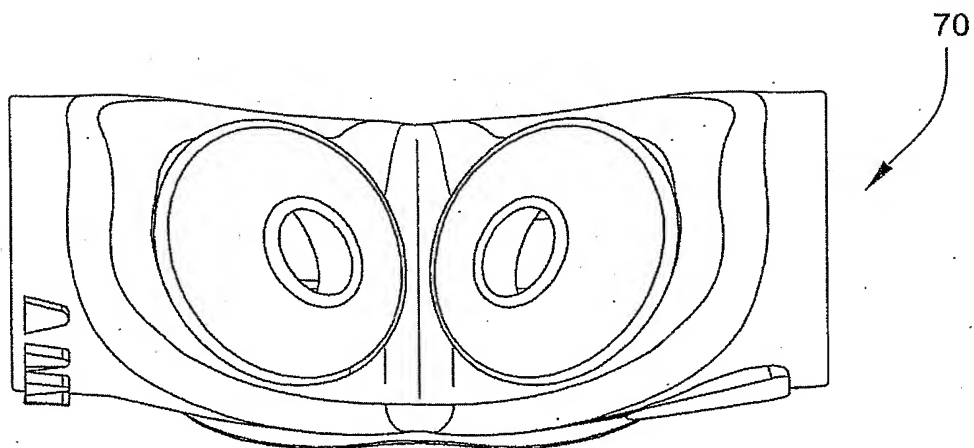


FIG. 13

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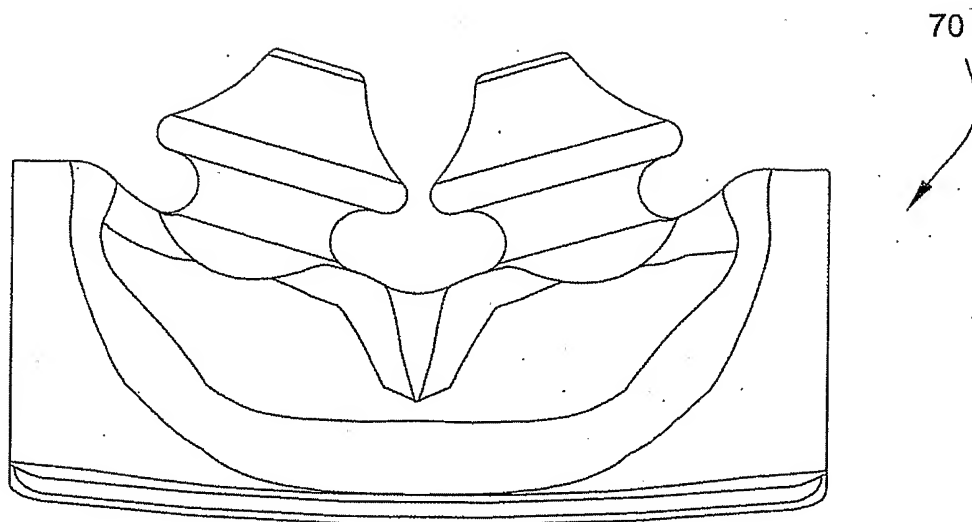


FIG. 14

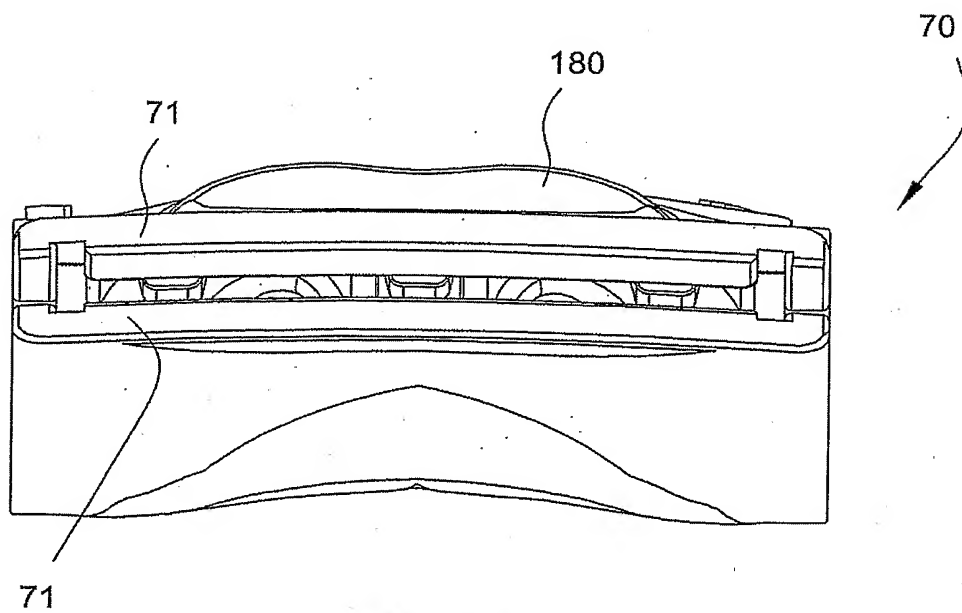
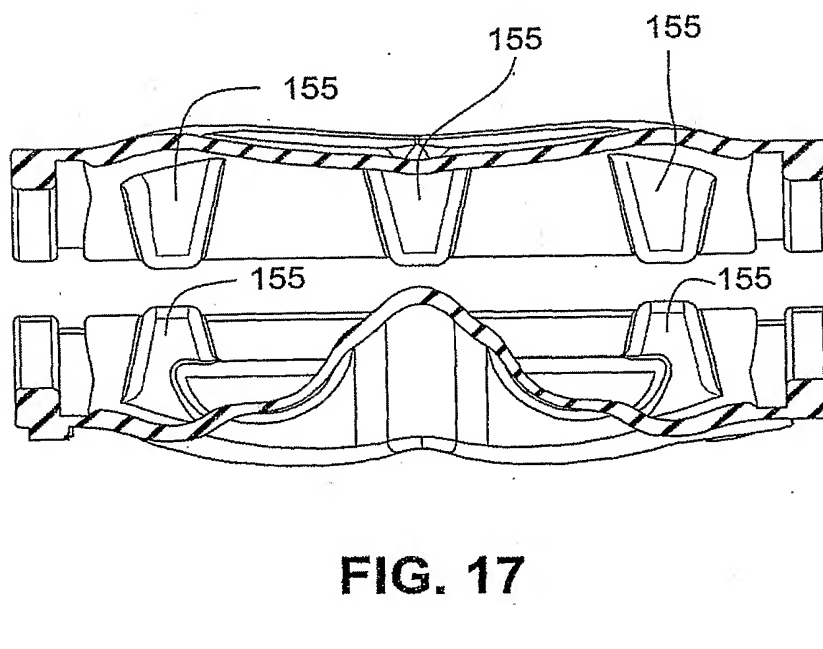
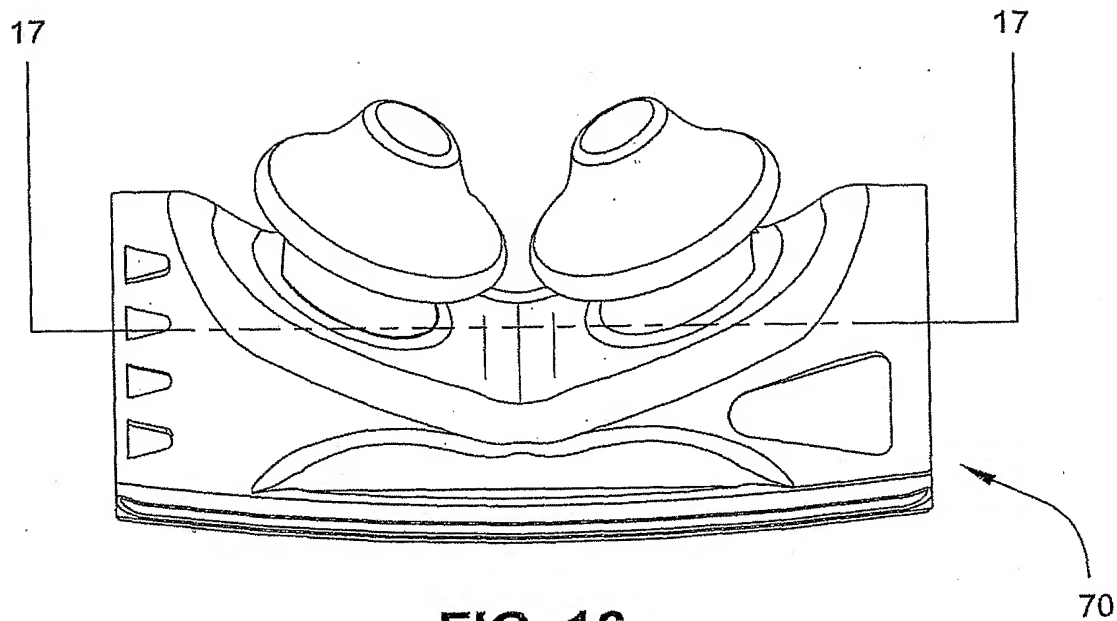
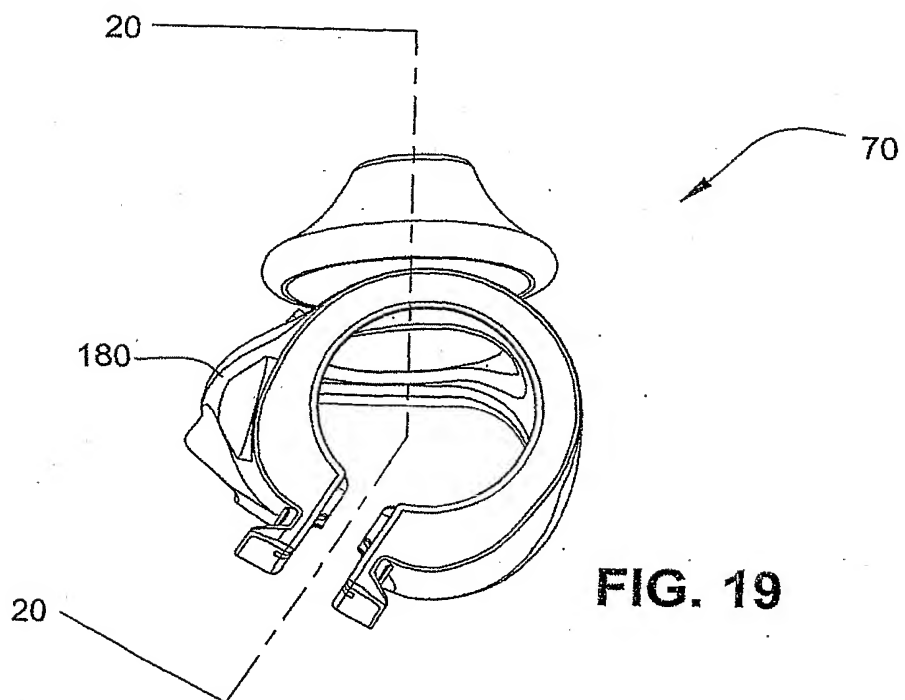
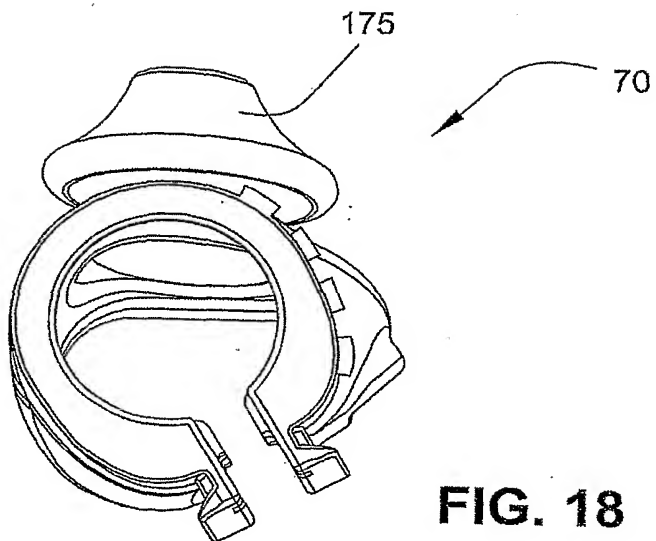


FIG. 15

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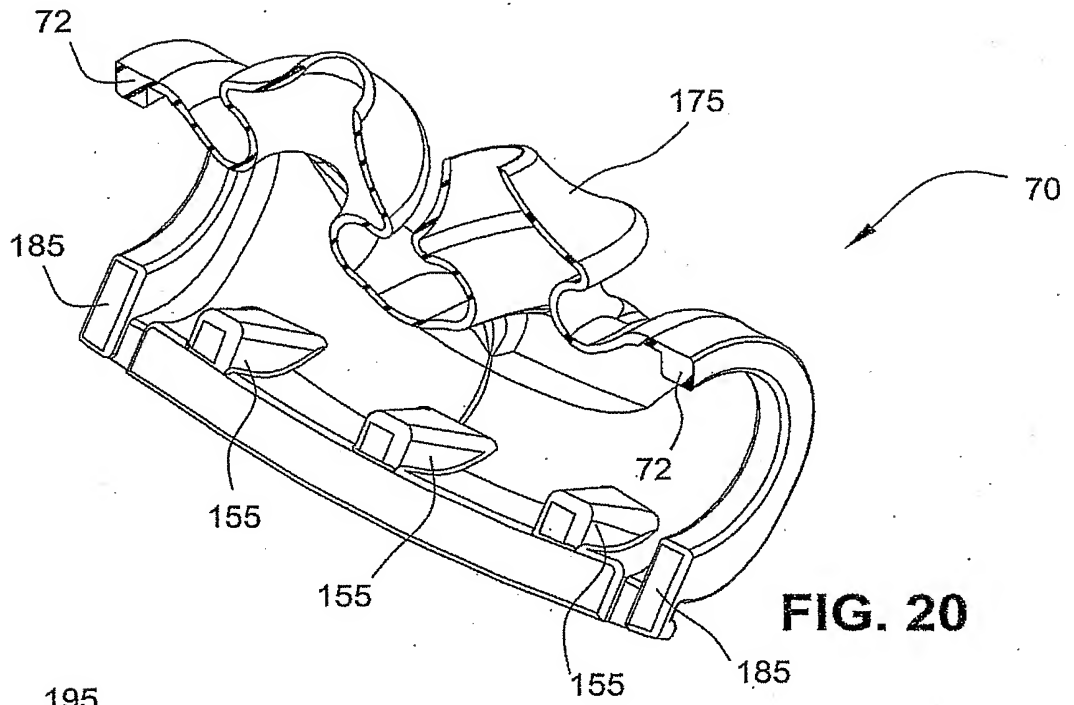


FIG. 20

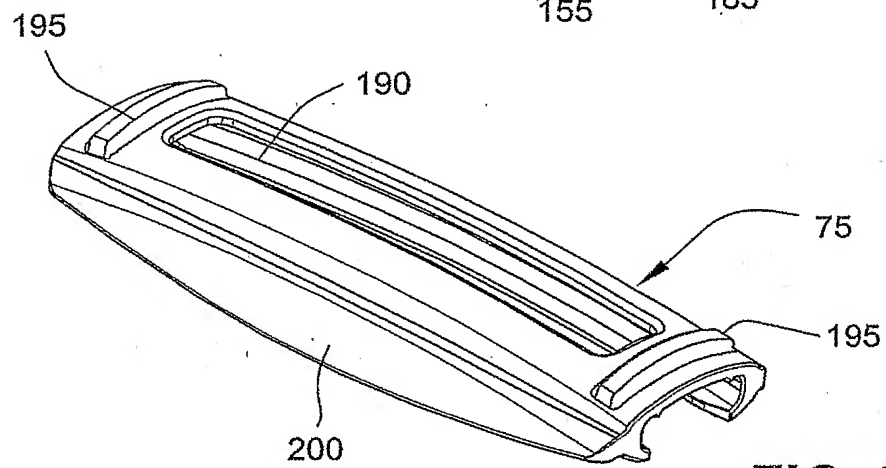


FIG. 21

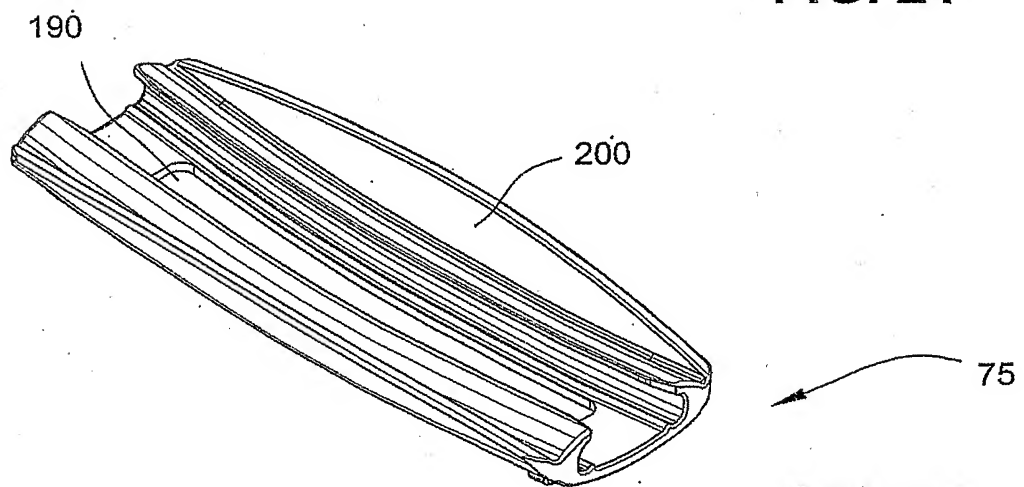
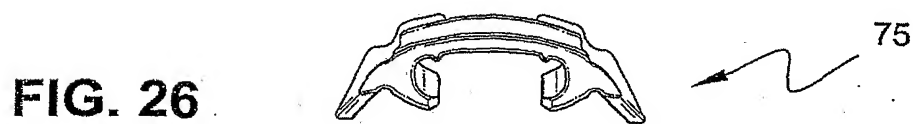
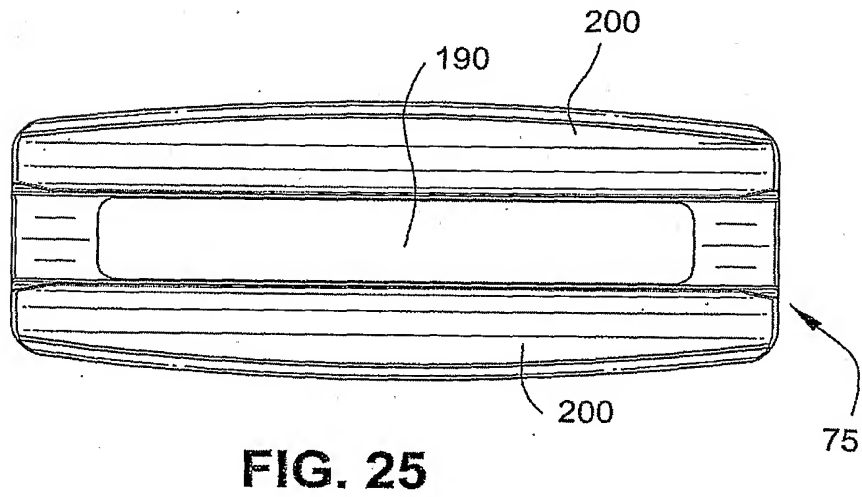
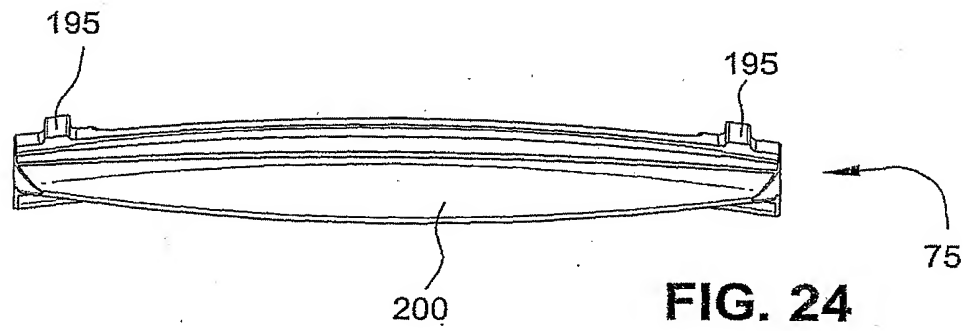
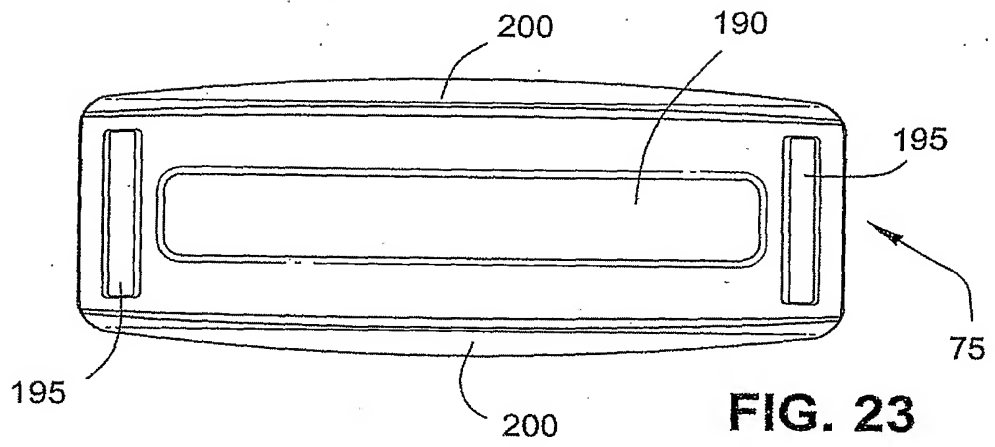


FIG. 22

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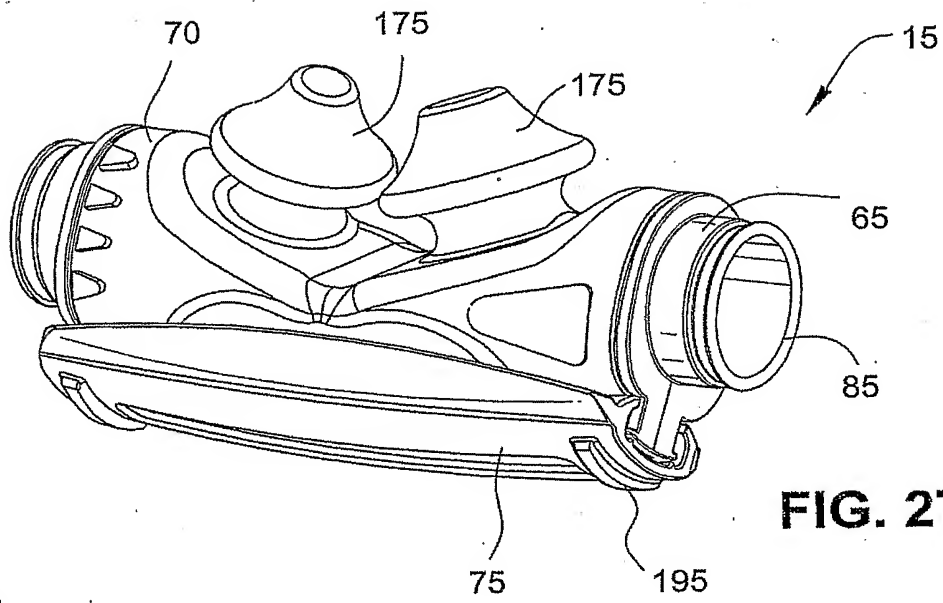


FIG. 27

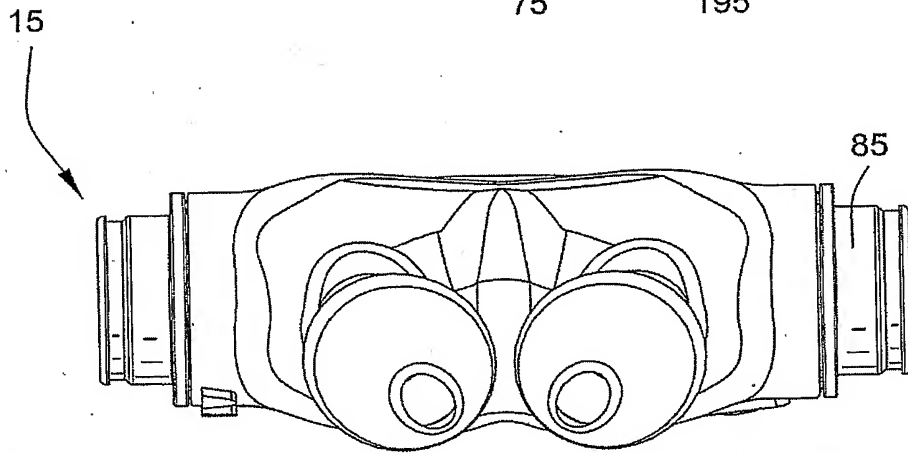


FIG. 28

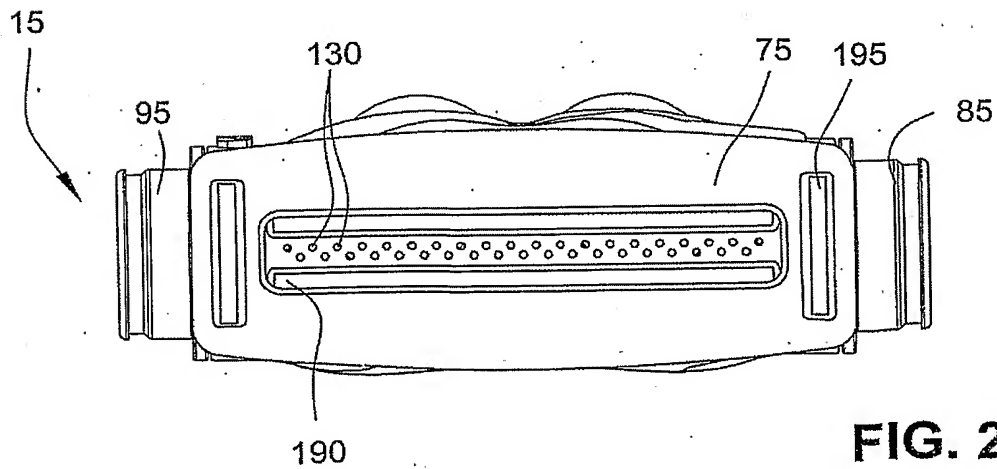


FIG. 29

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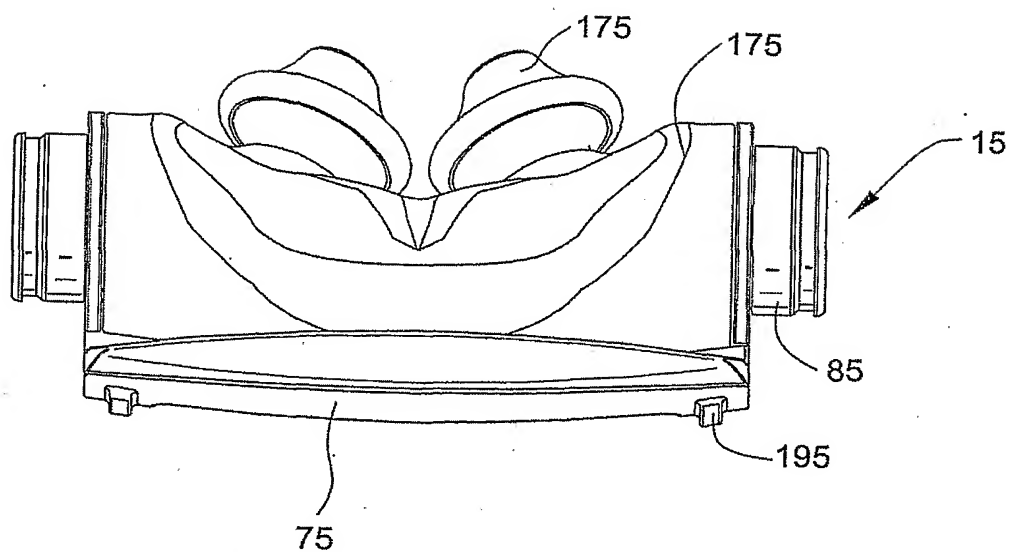


FIG. 30

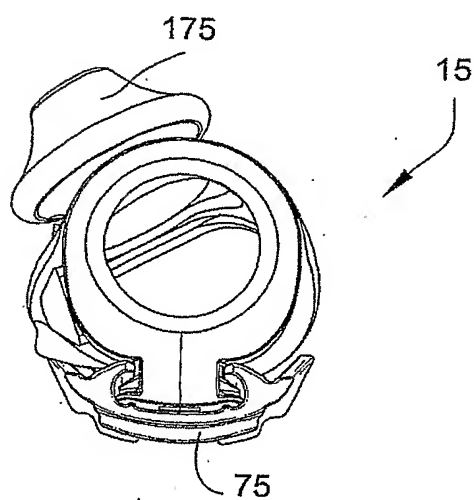


FIG. 31

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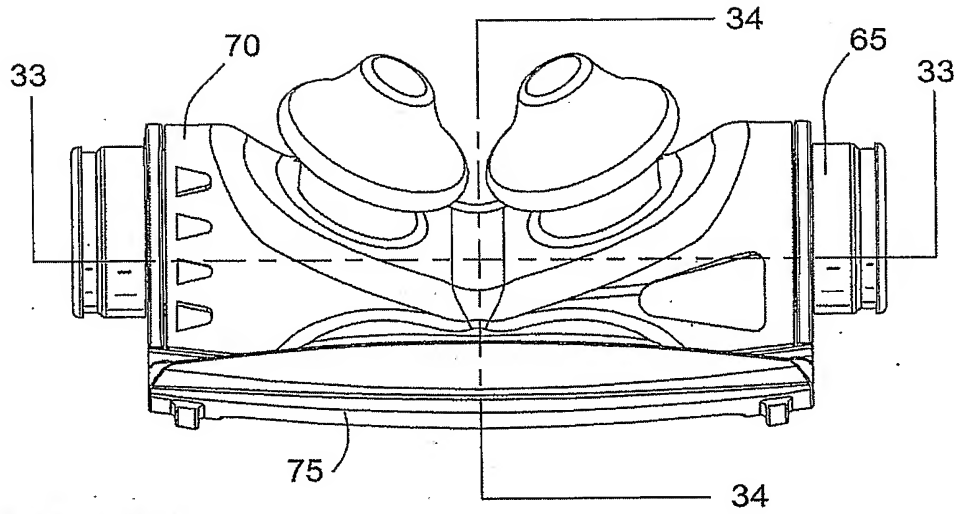


FIG. 32

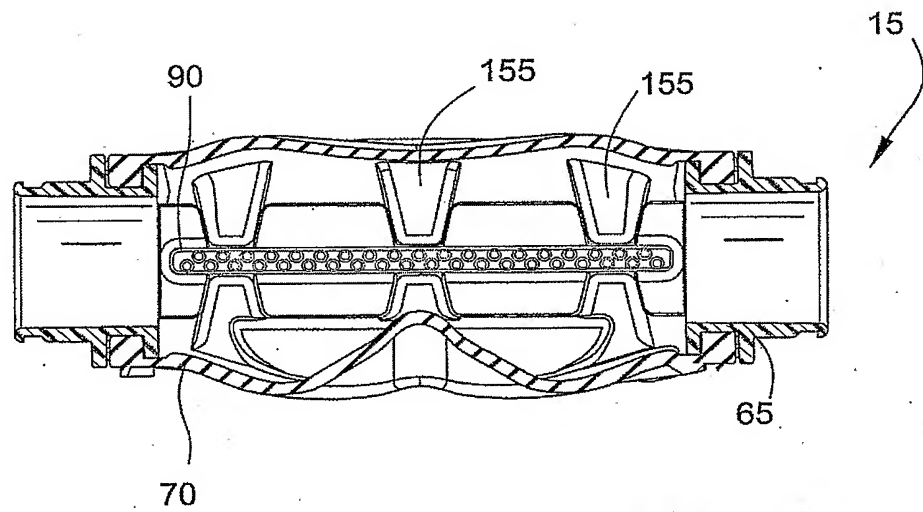


FIG. 33

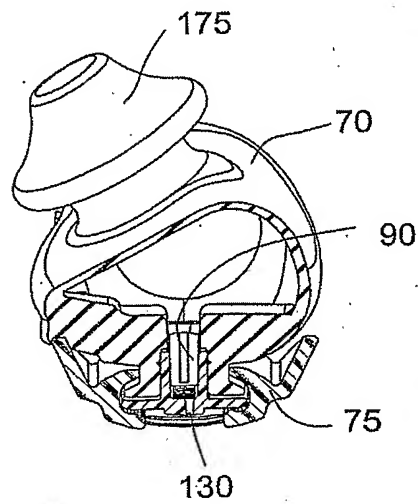


FIG. 34

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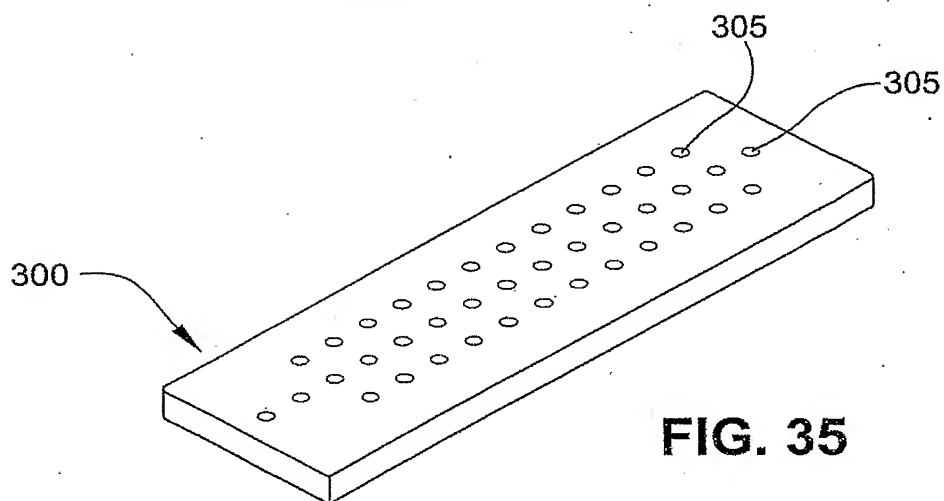


FIG. 35

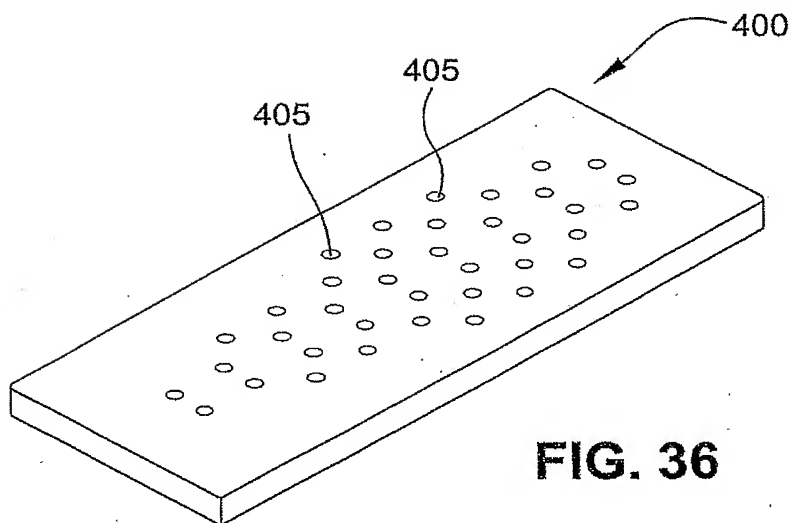


FIG. 36

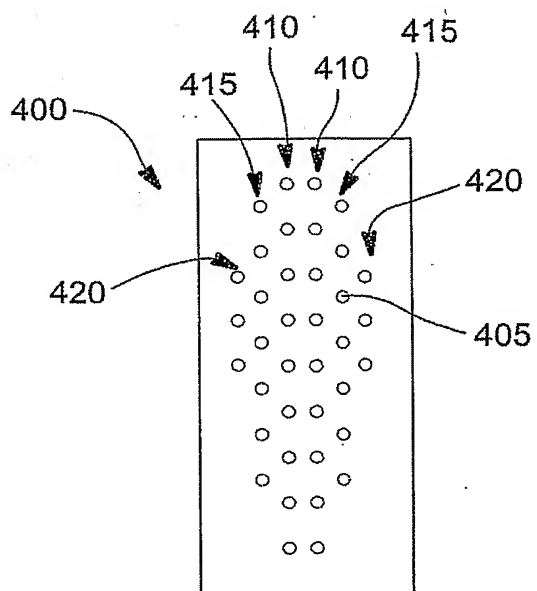


FIG. 37

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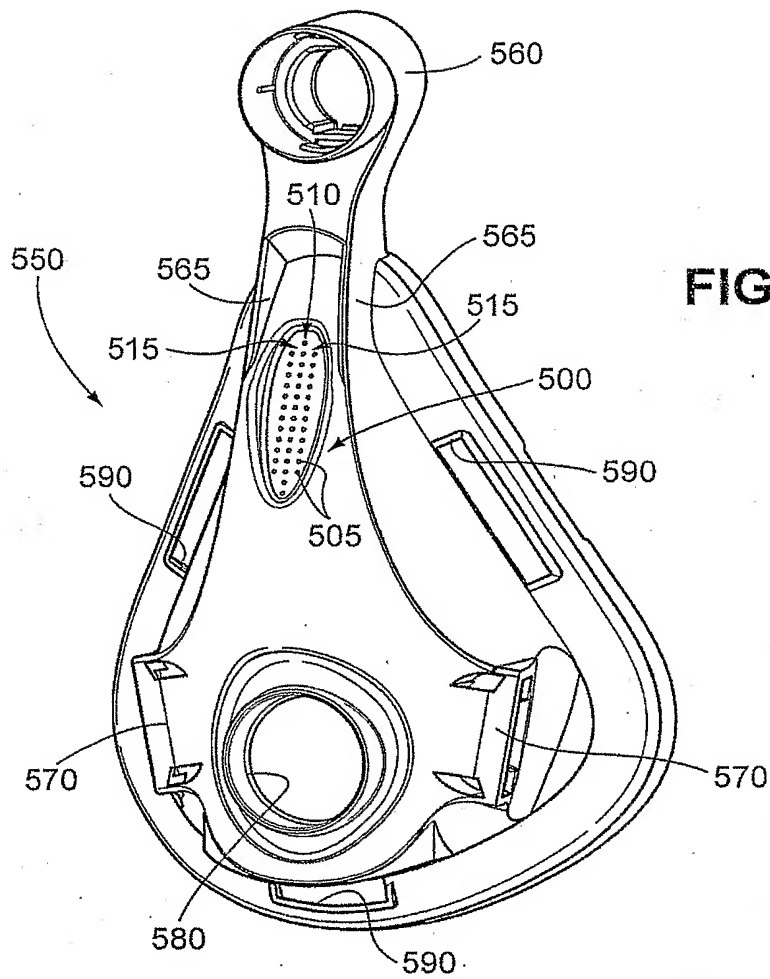
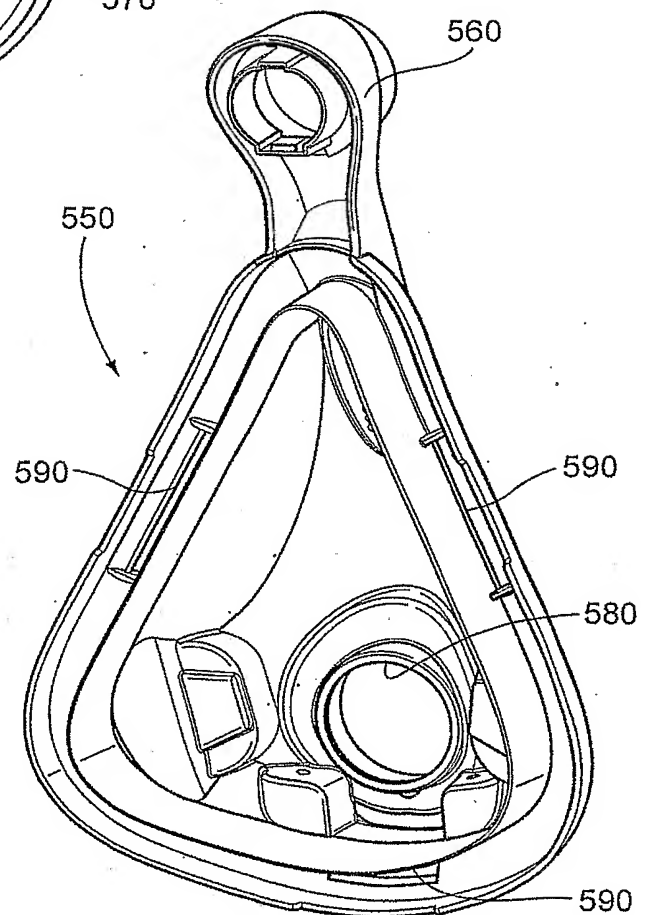


FIG. 38

FIG. 39



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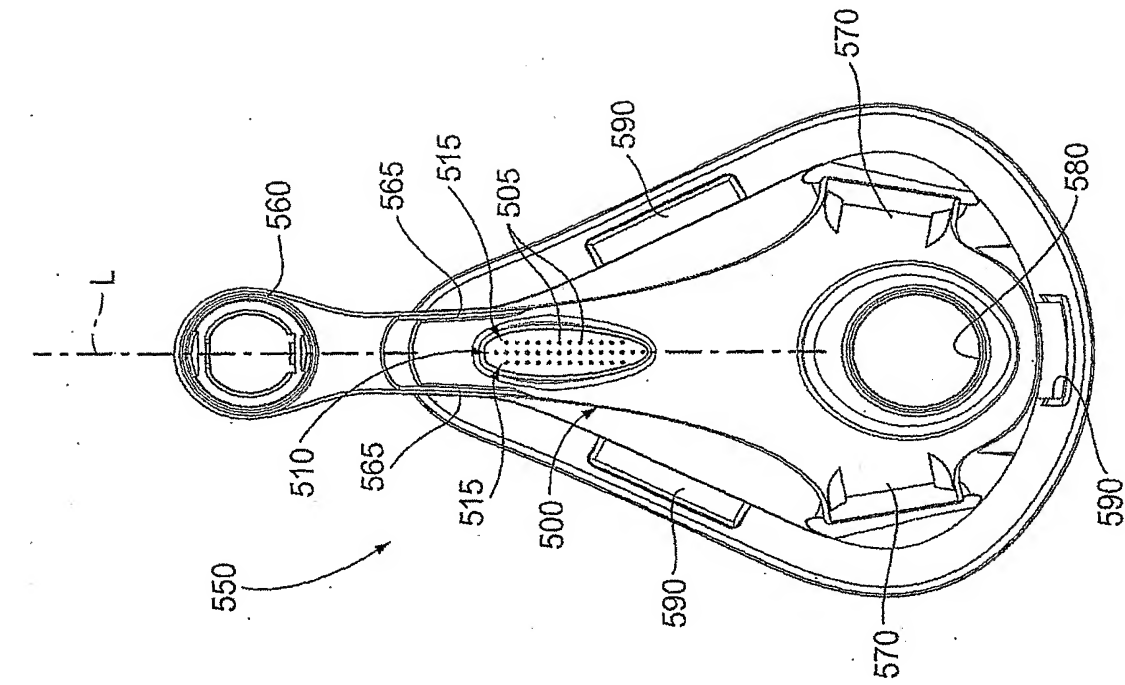


FIG. 41

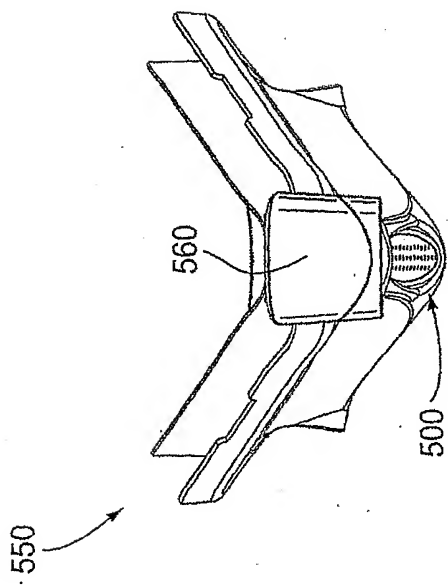


FIG. 40

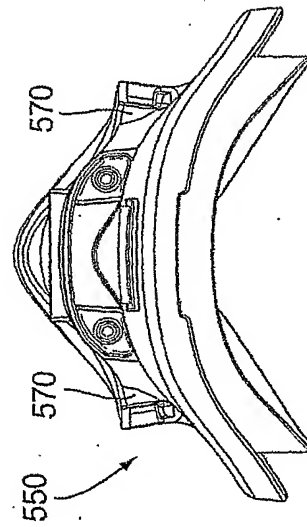


FIG. 42

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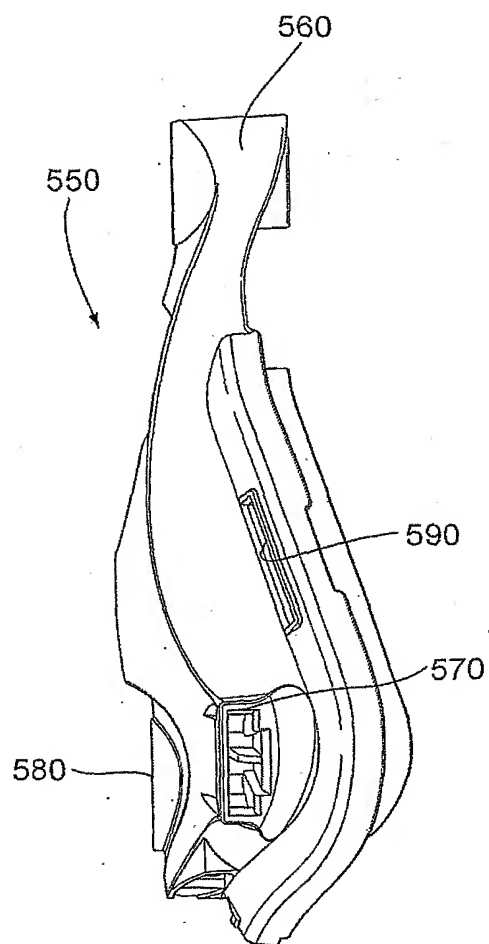


FIG. 43

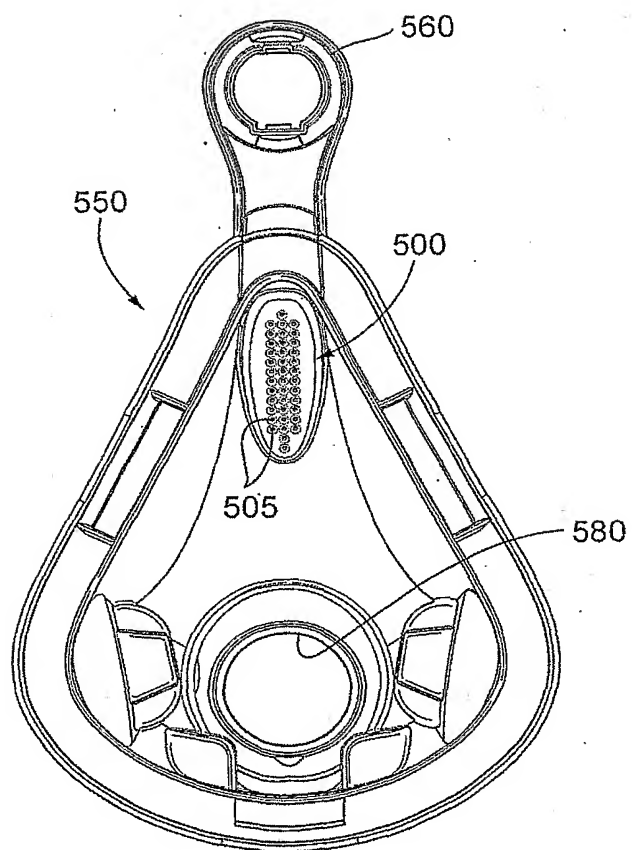


FIG. 44

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FIG. 45

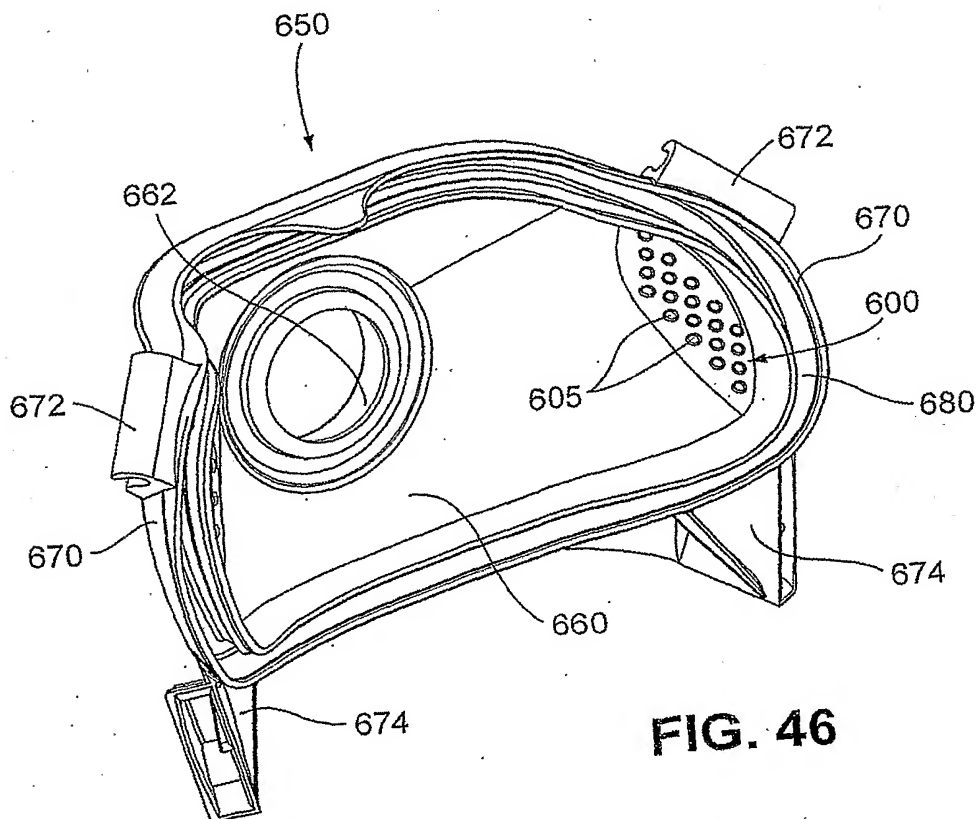
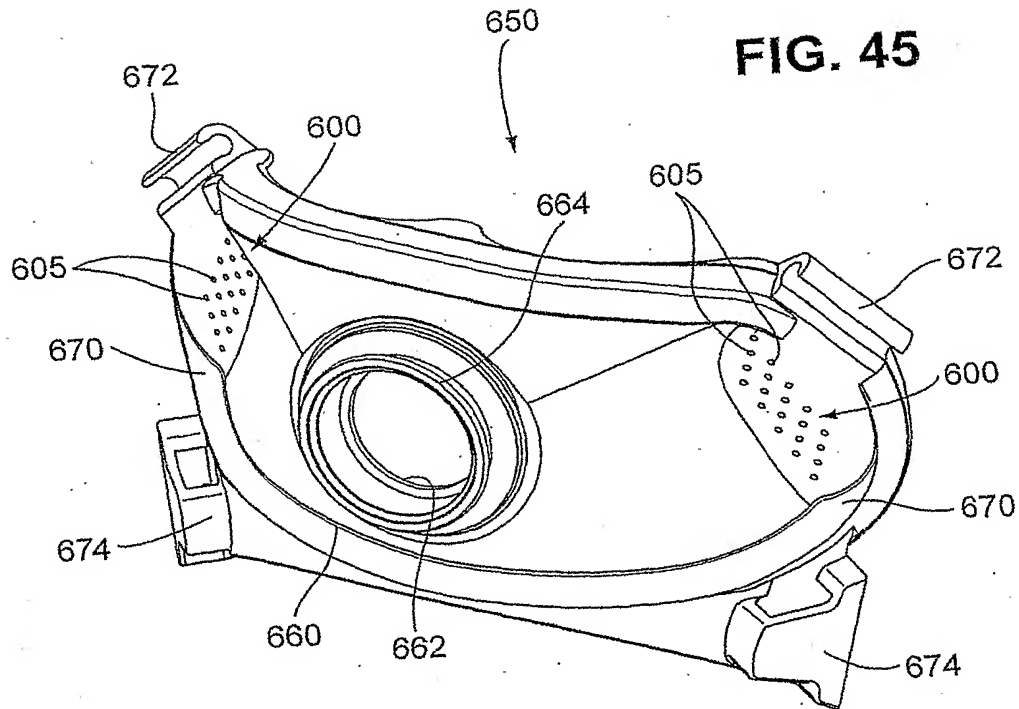
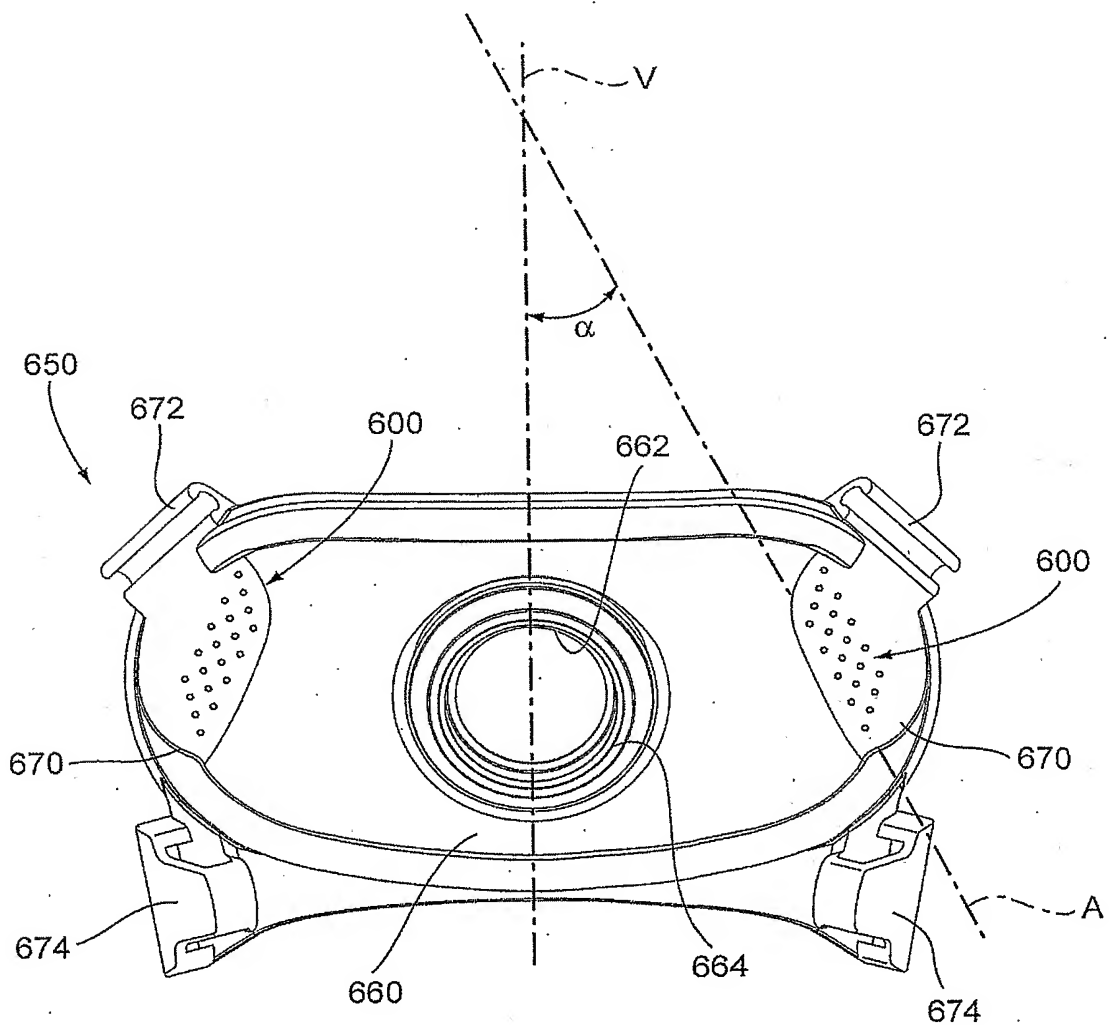
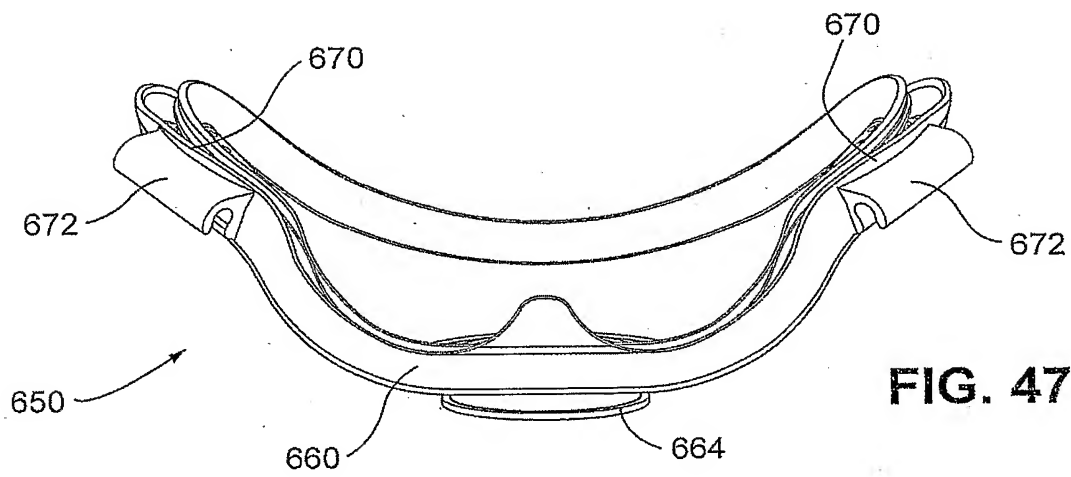


FIG. 46

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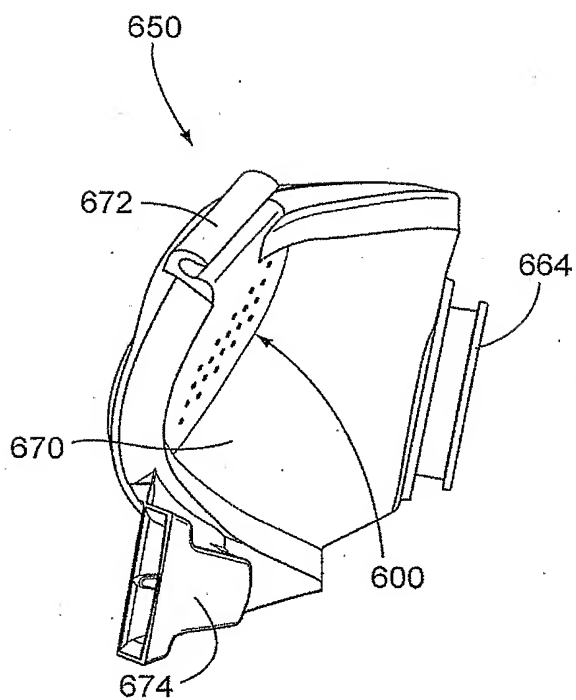


FIG. 49

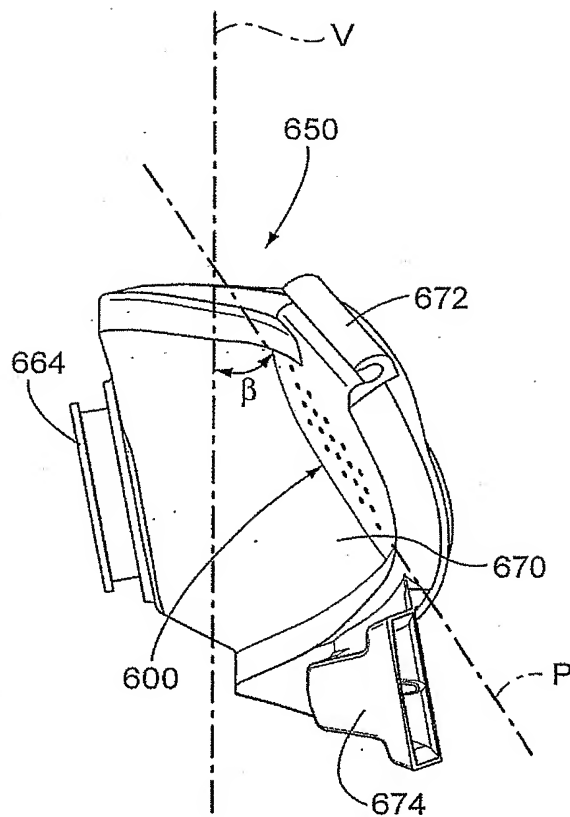


FIG. 50

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FIG. 51

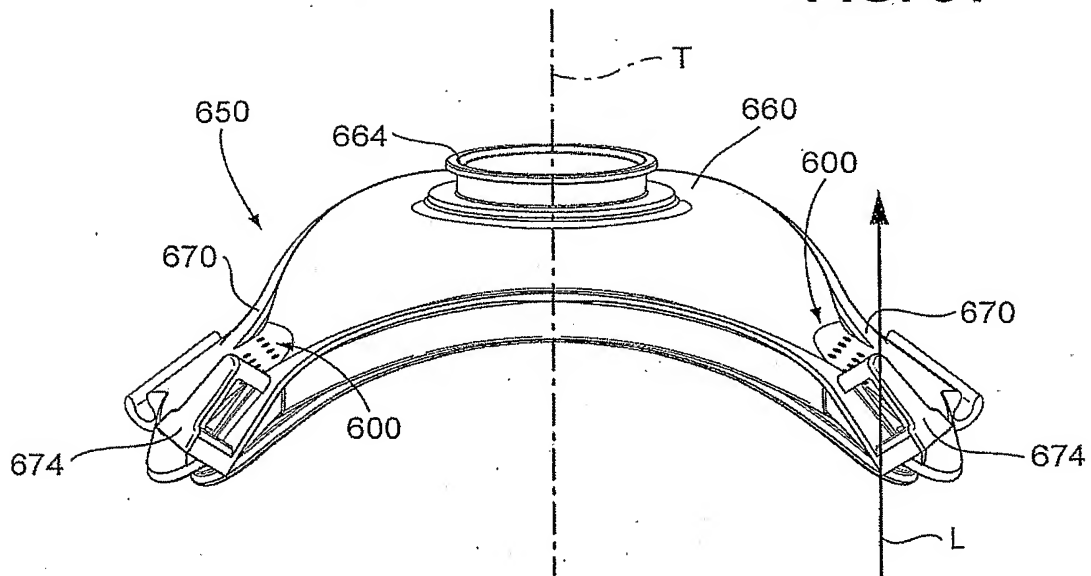
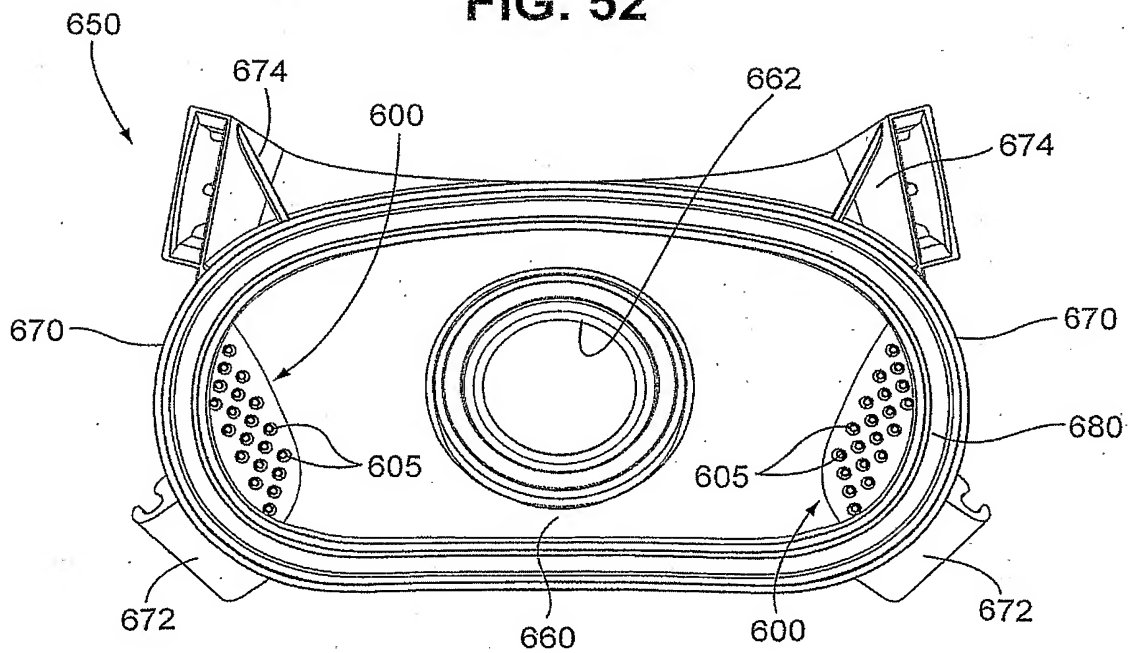


FIG. 52



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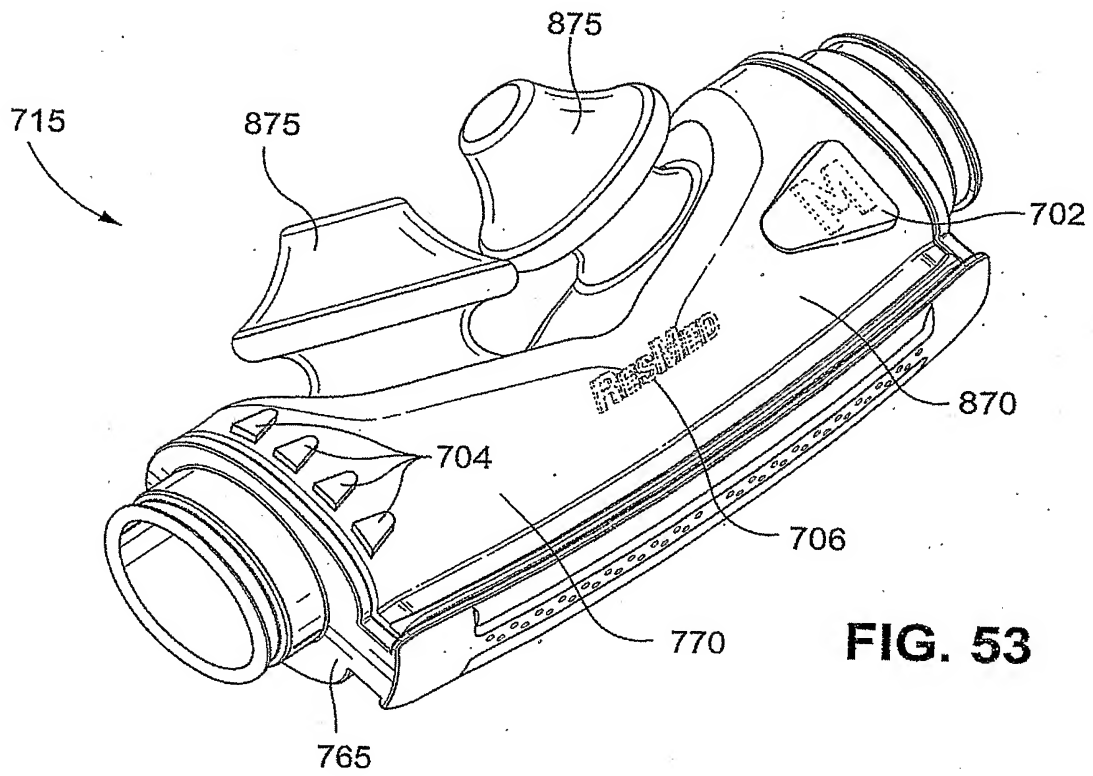


FIG. 53

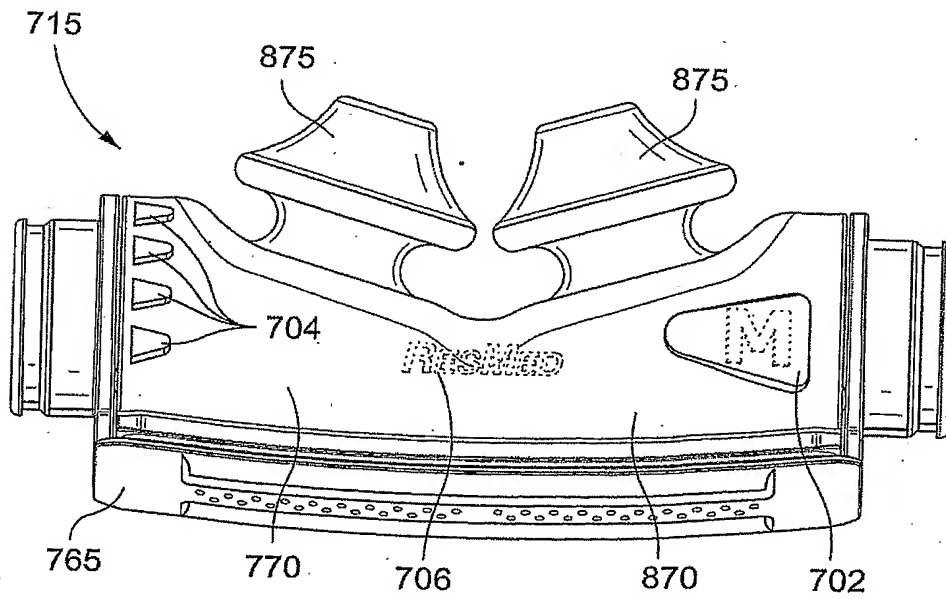


FIG. 54

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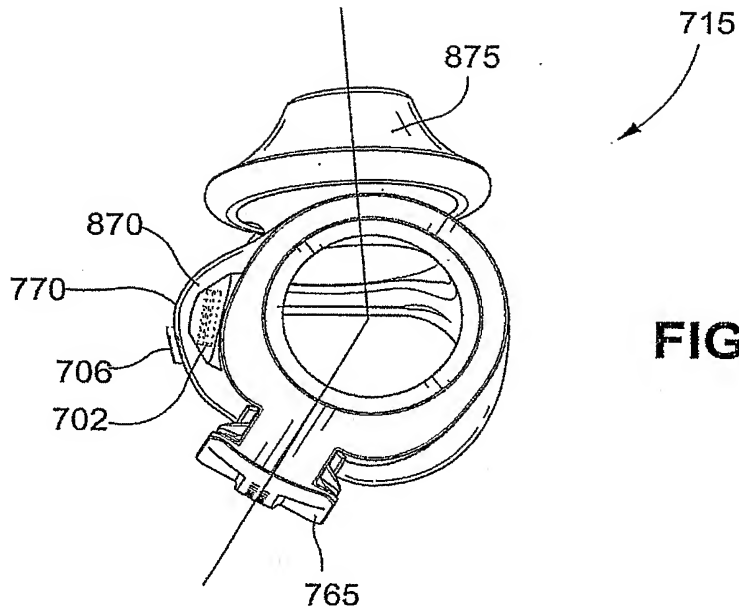


FIG. 55

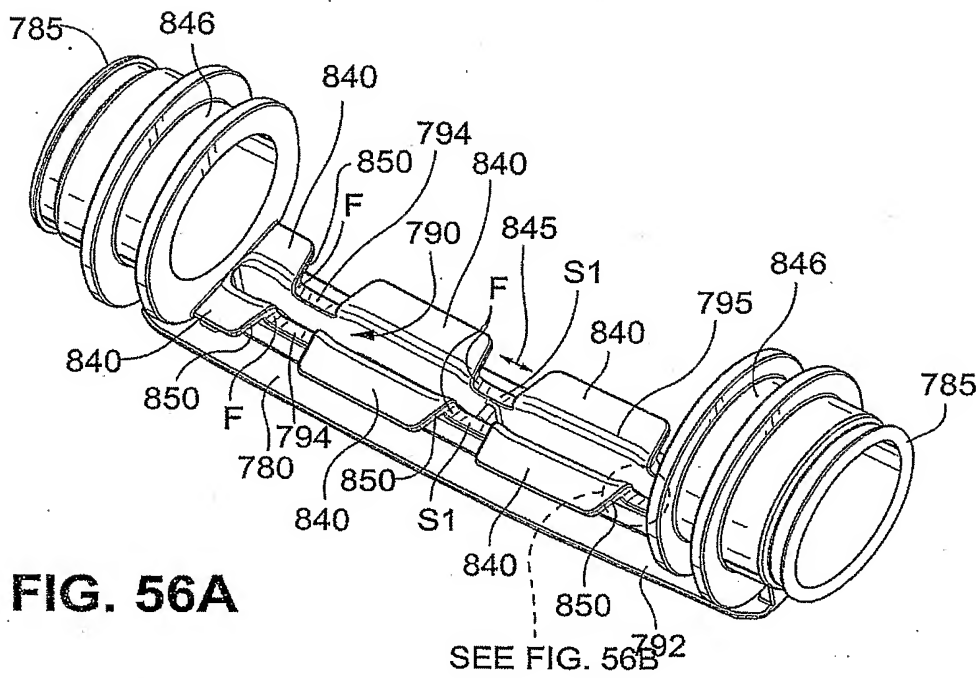


FIG. 56A

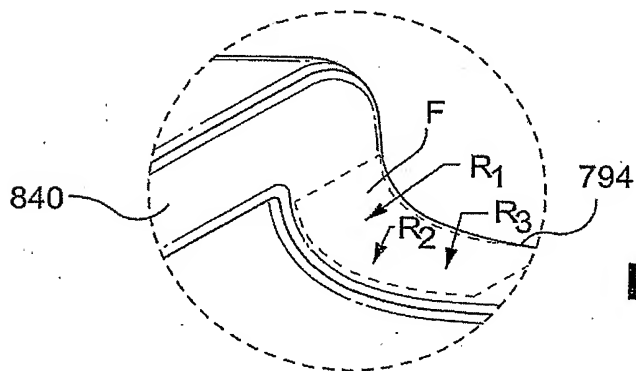


FIG. 56B

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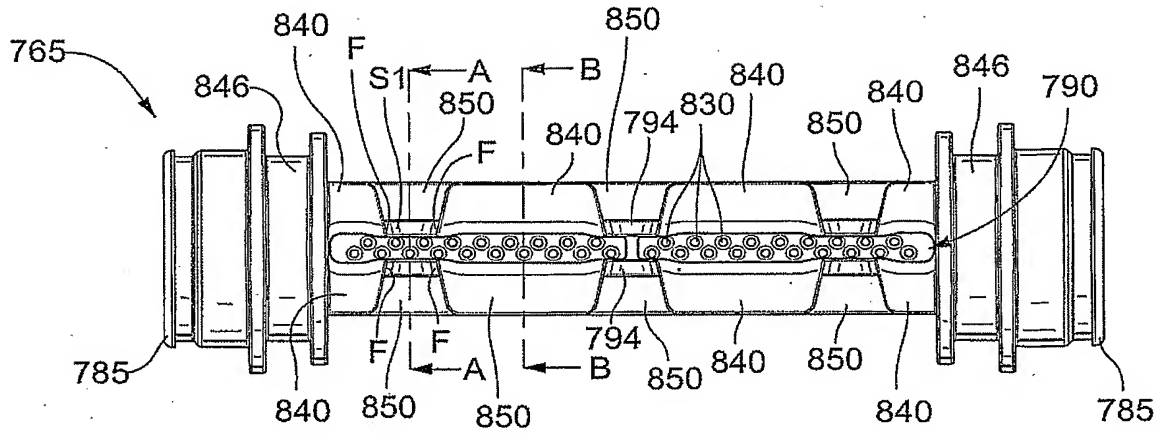


FIG. 57

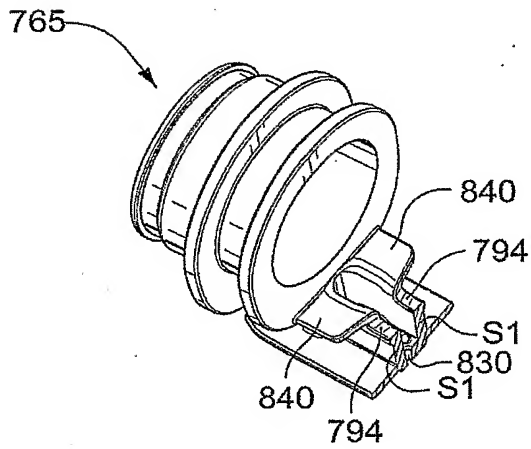


FIG. 58

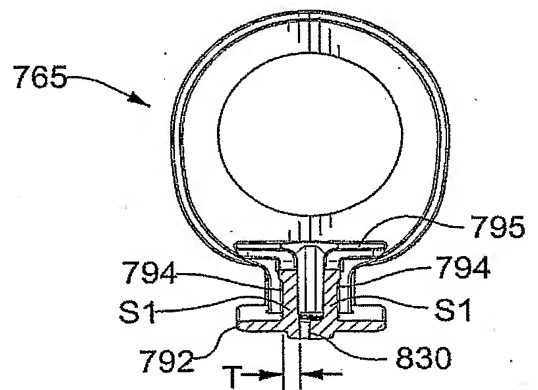


FIG. 59

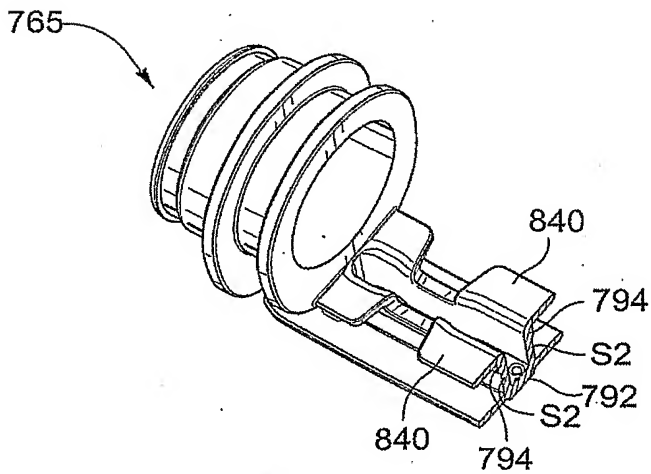


FIG. 60

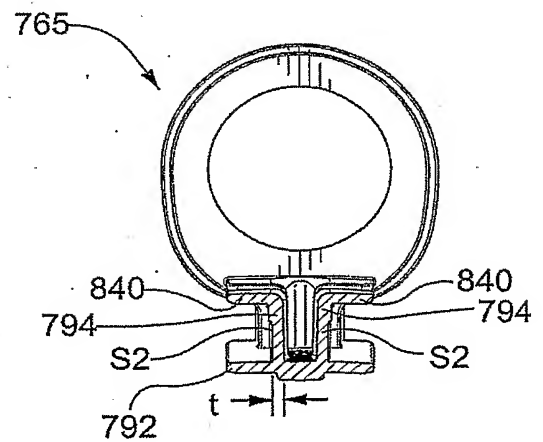
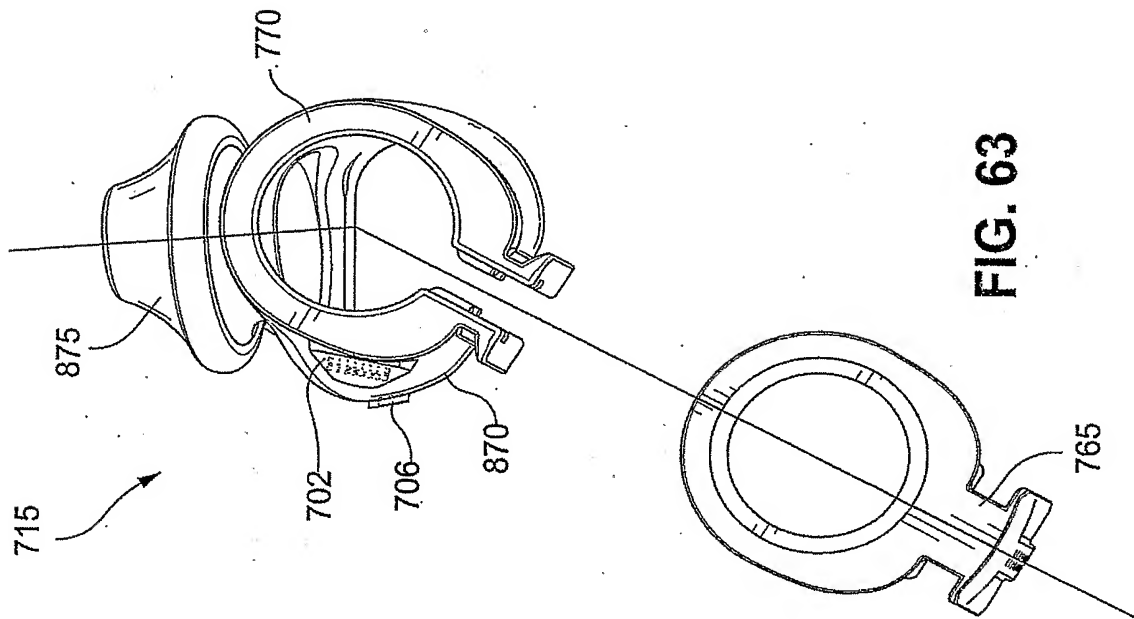
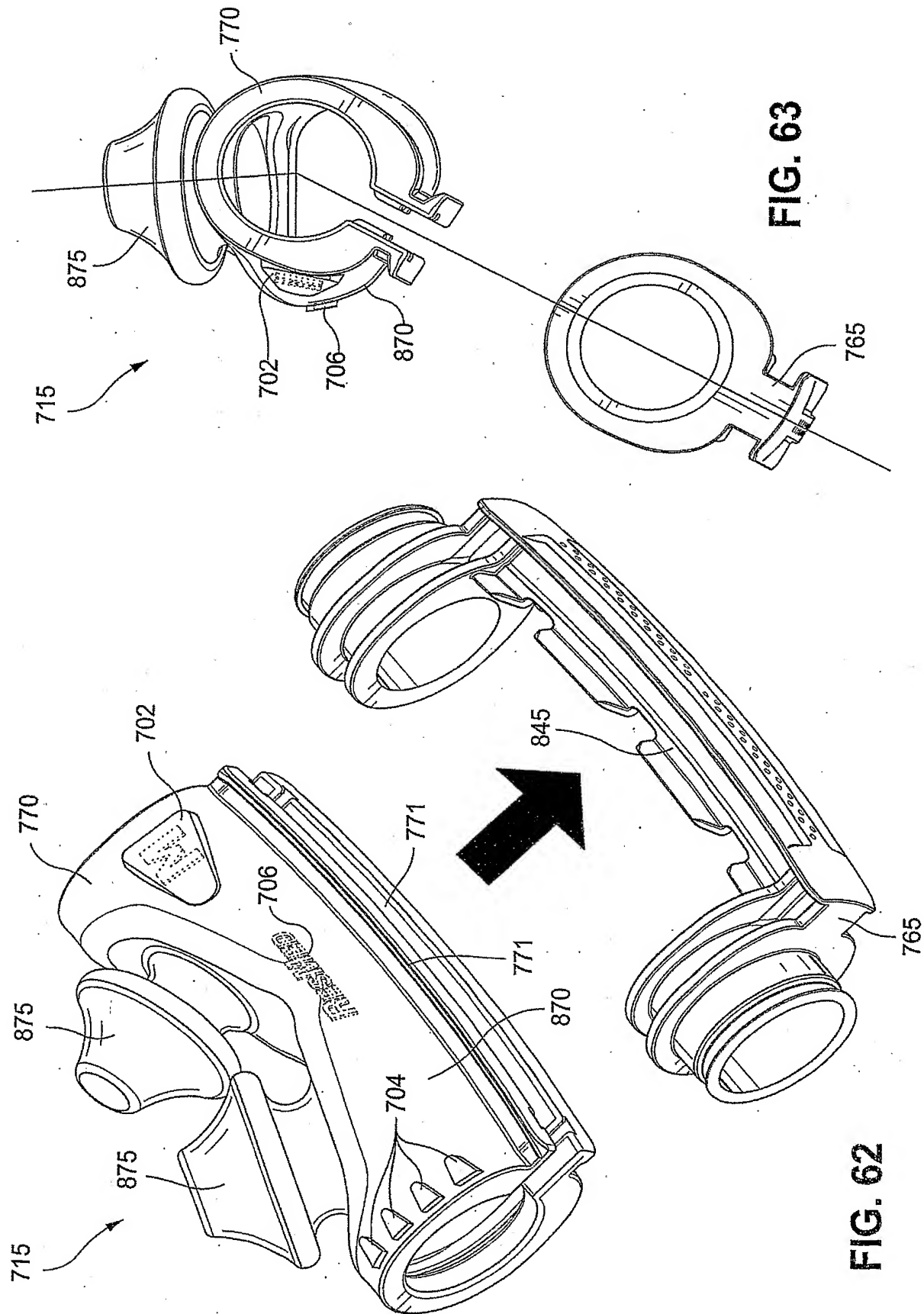


FIG. 61

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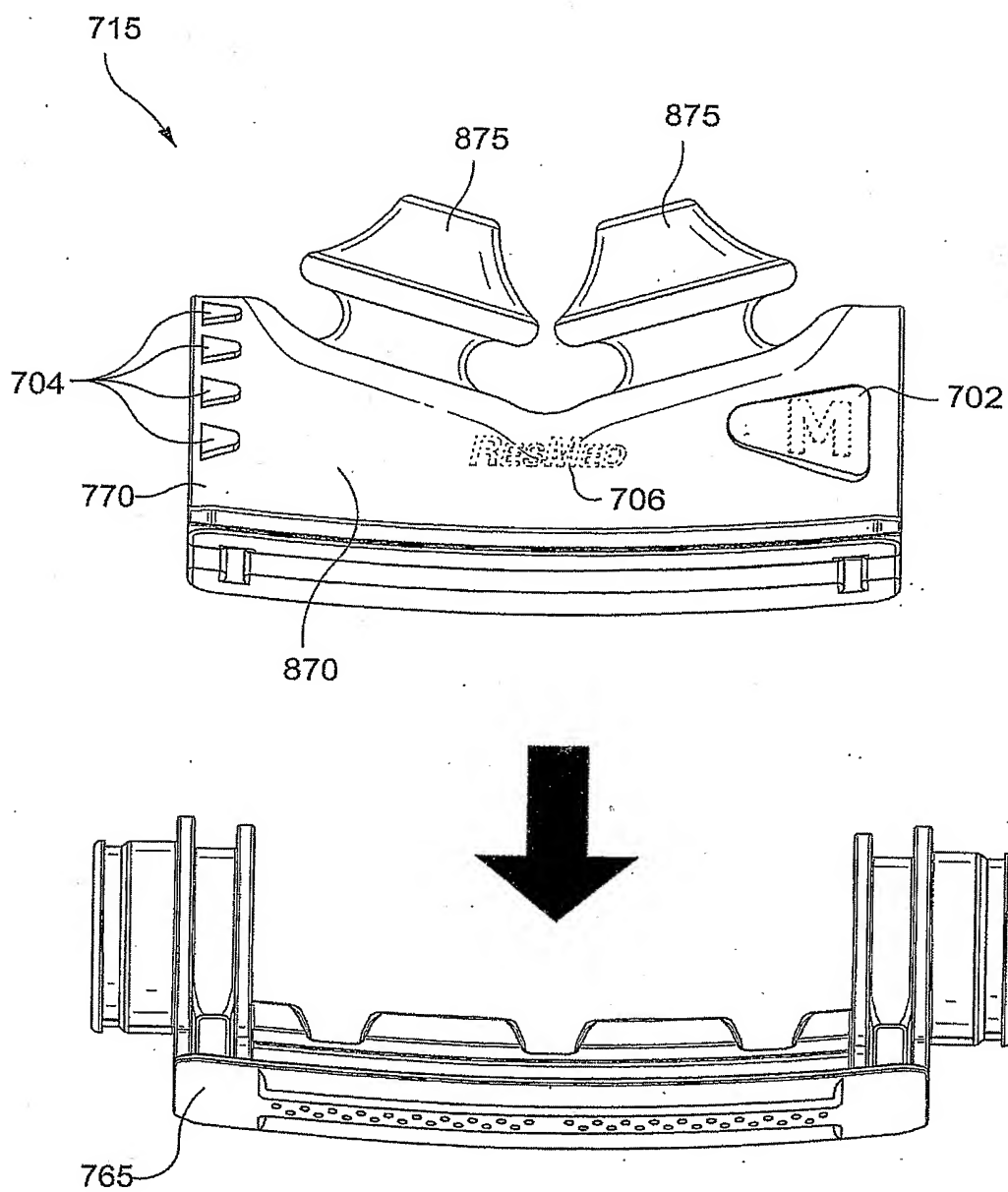


FIG. 64

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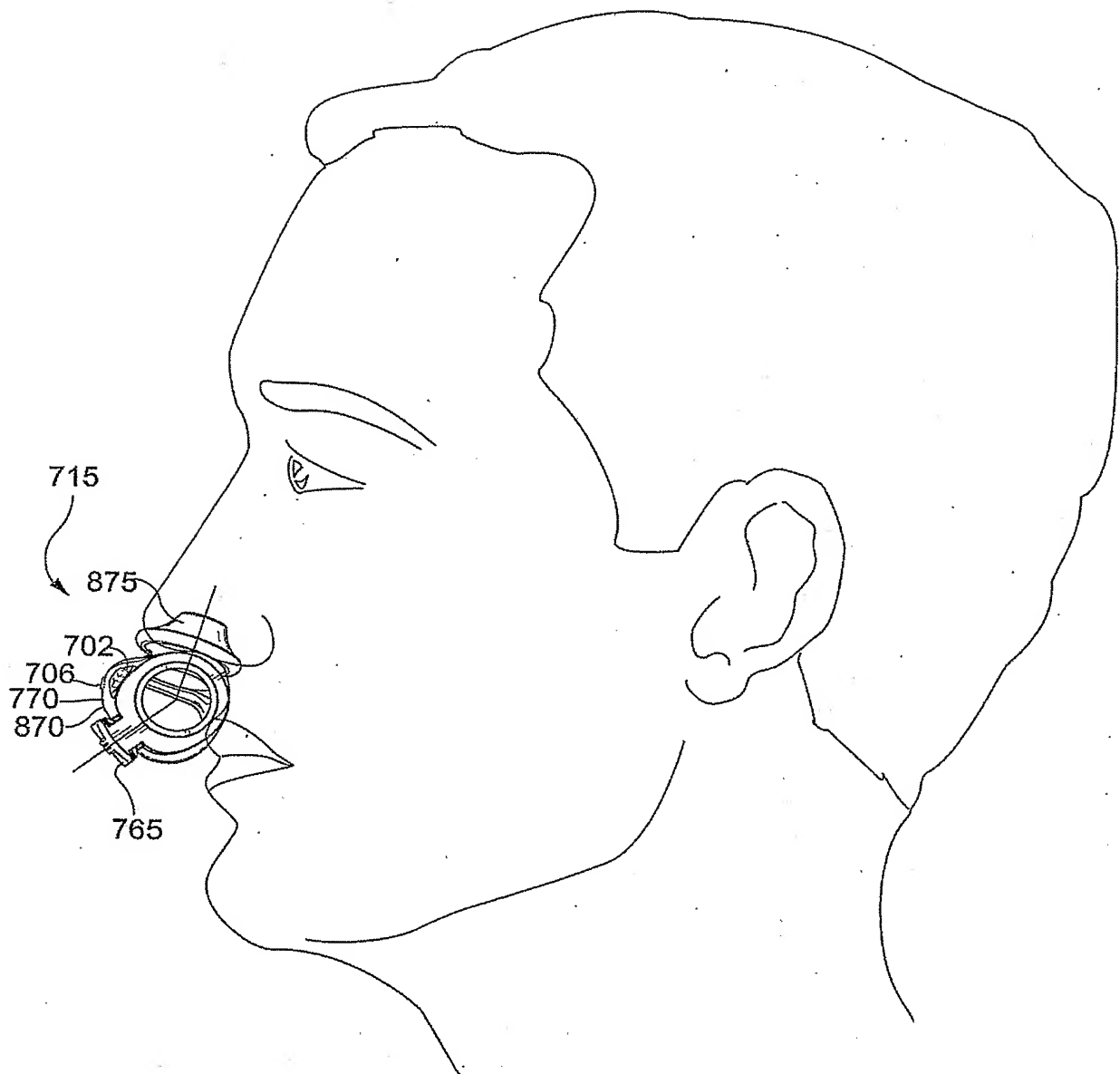


FIG. 65

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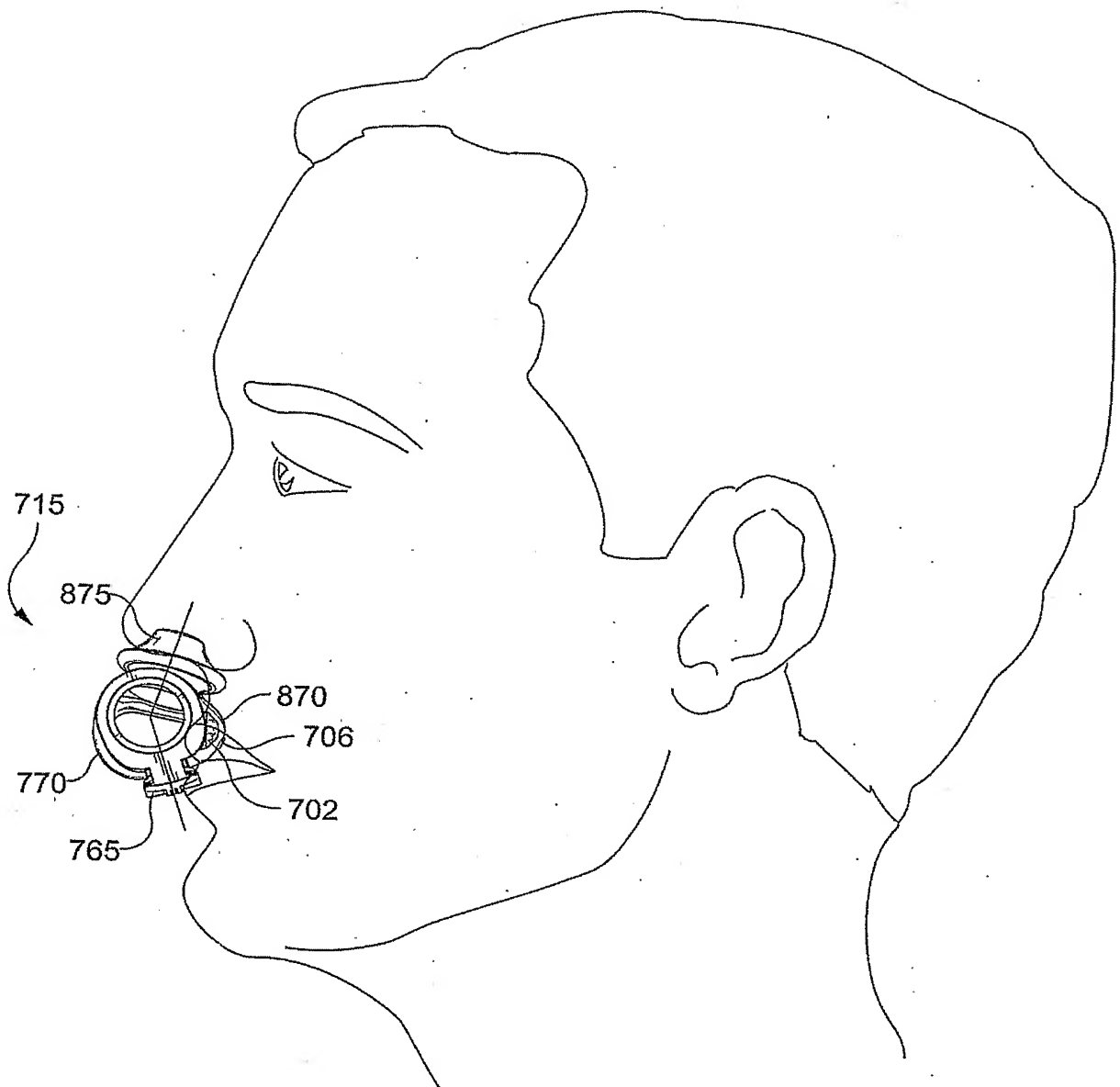


FIG. 66

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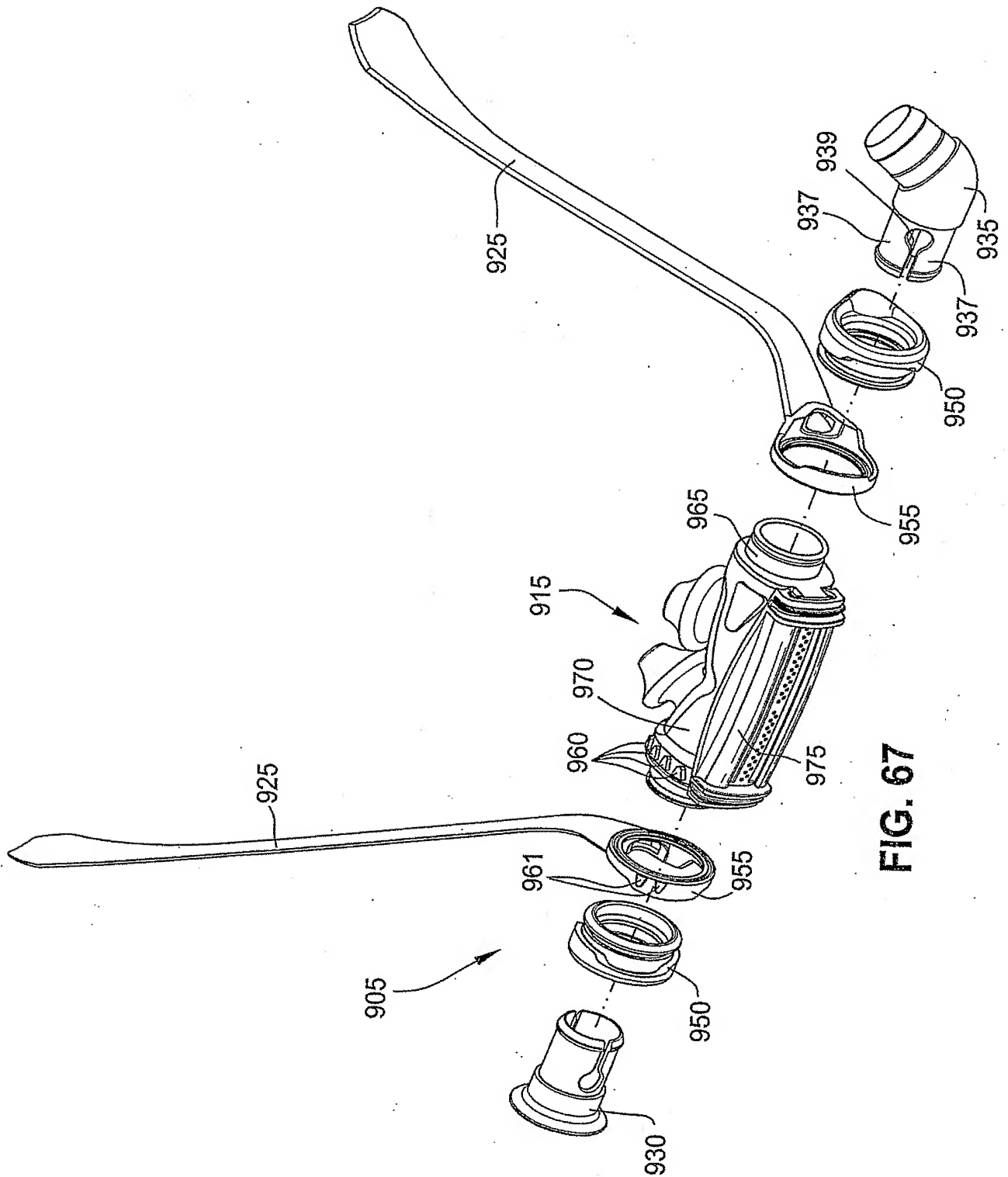


FIG. 67

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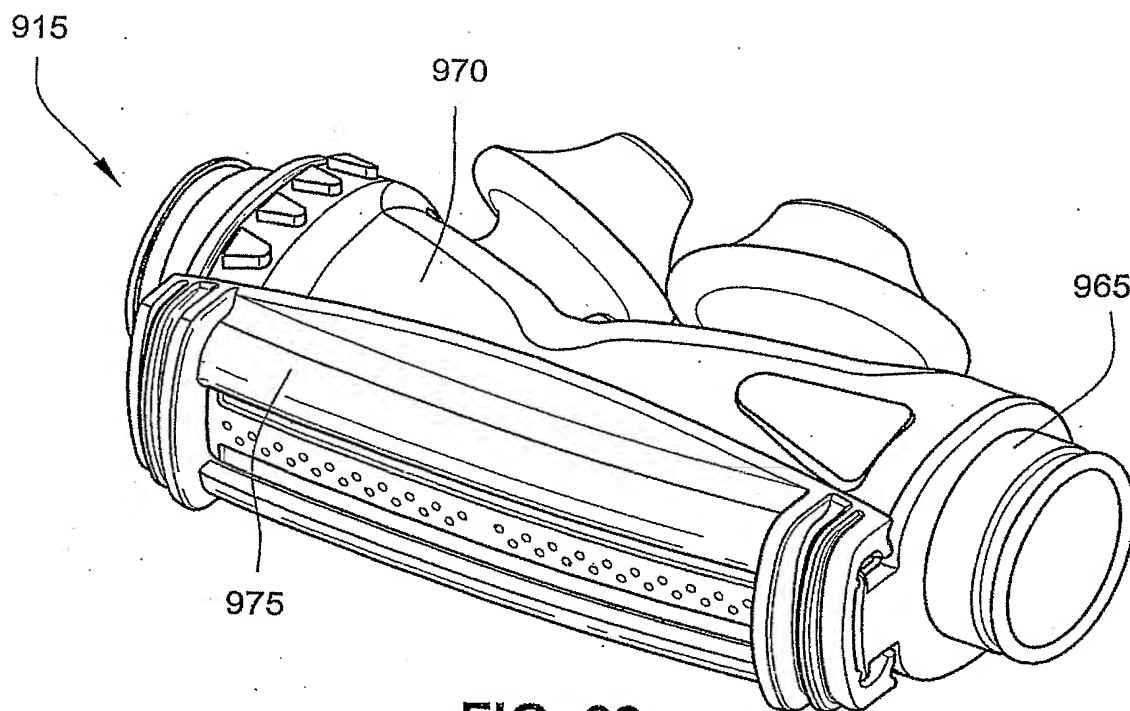


FIG. 68

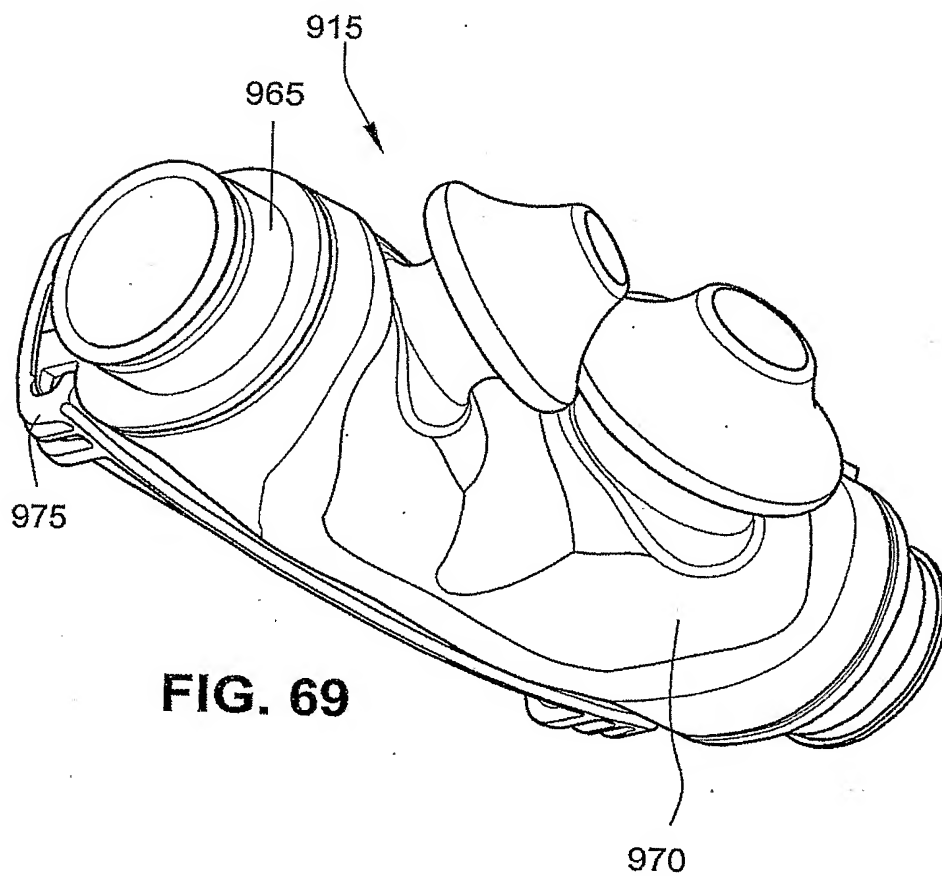
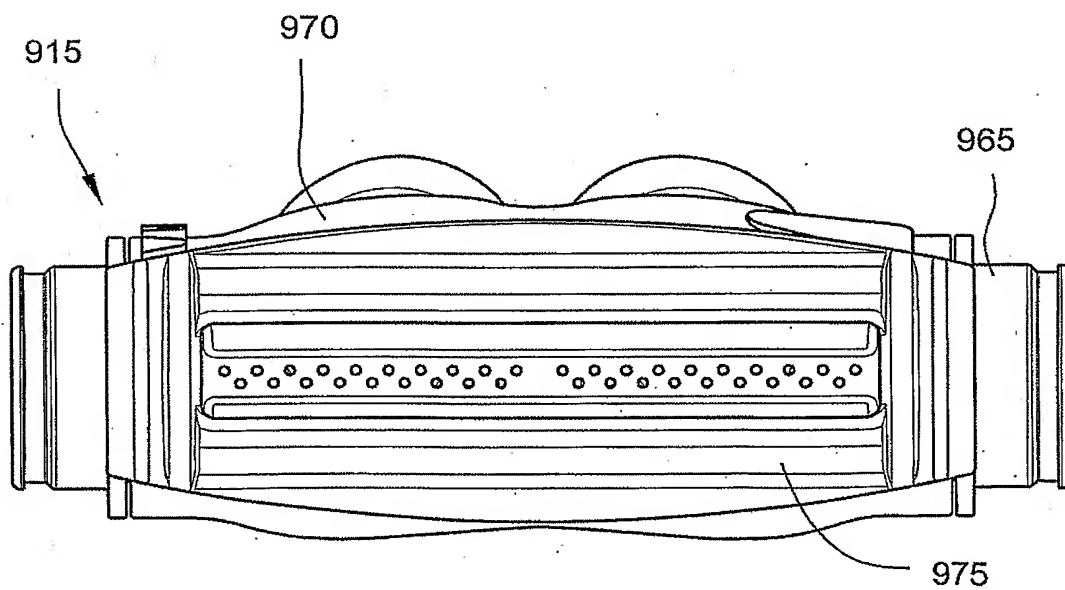
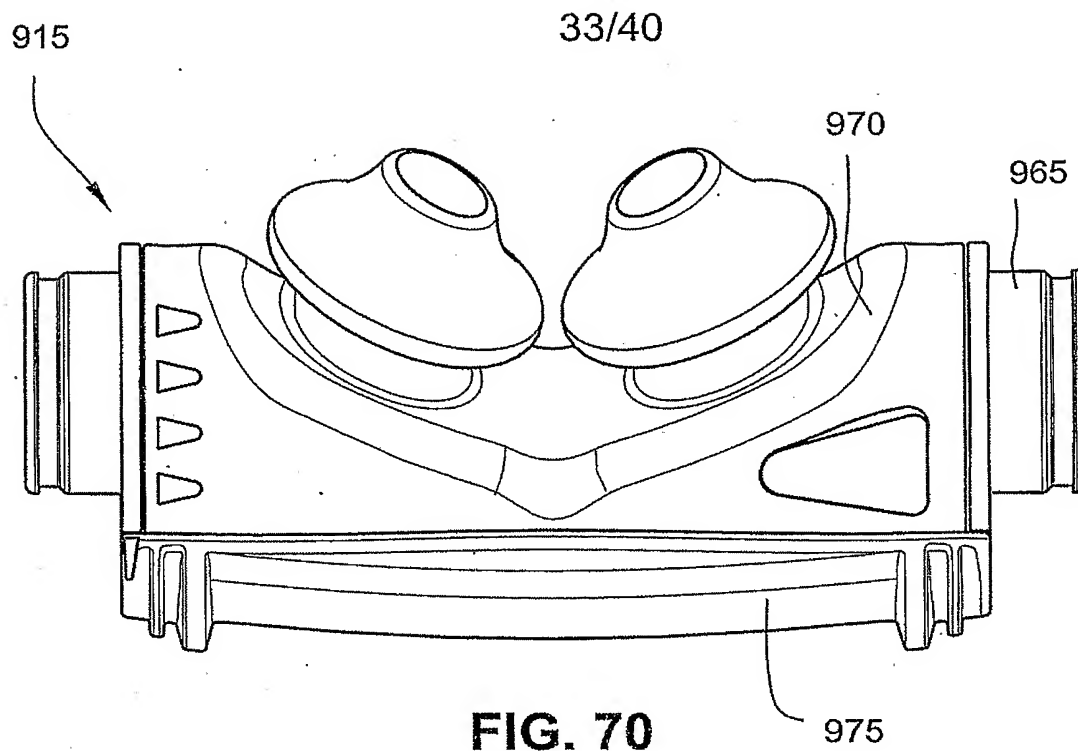


FIG. 69



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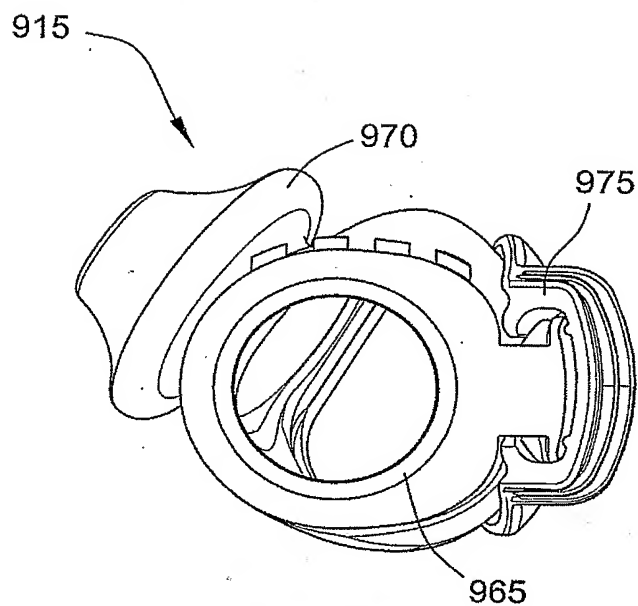


FIG. 72

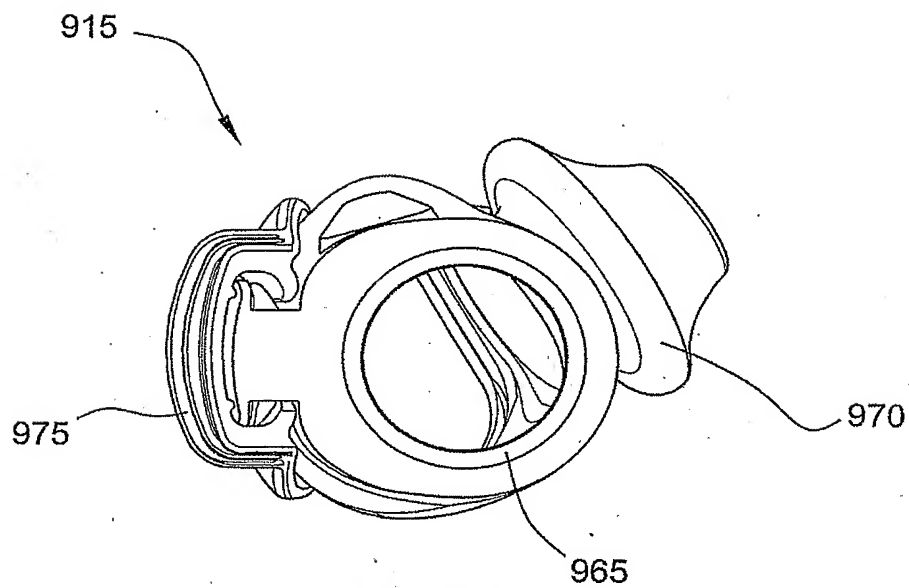


FIG. 73

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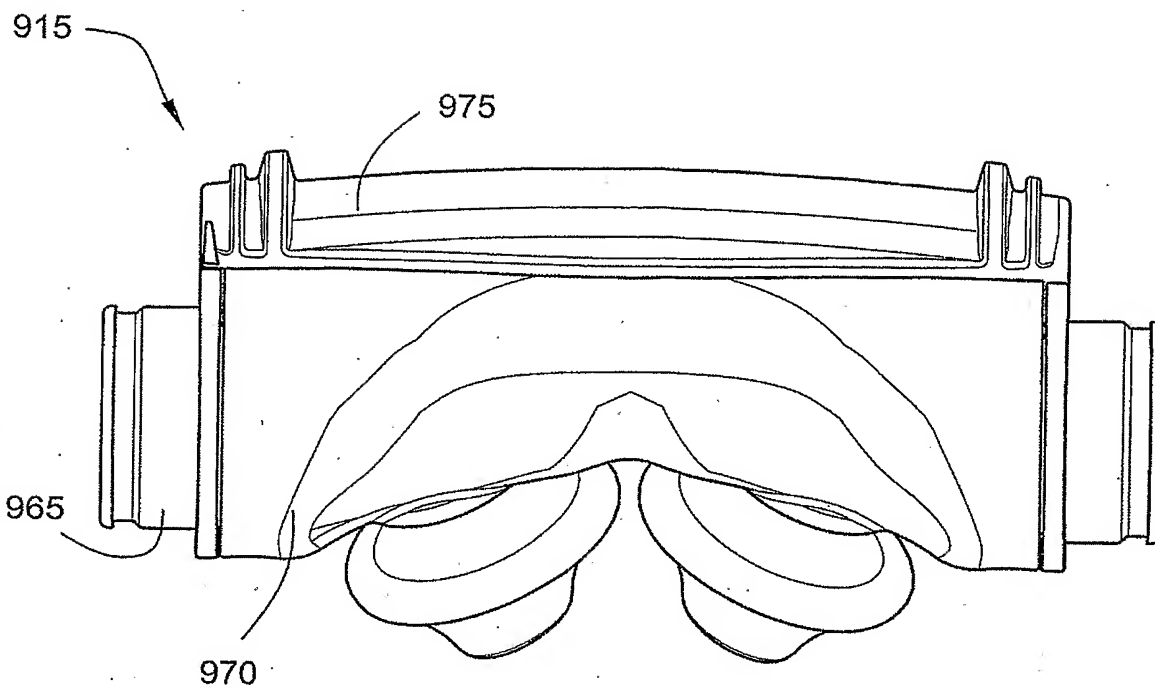


FIG. 74

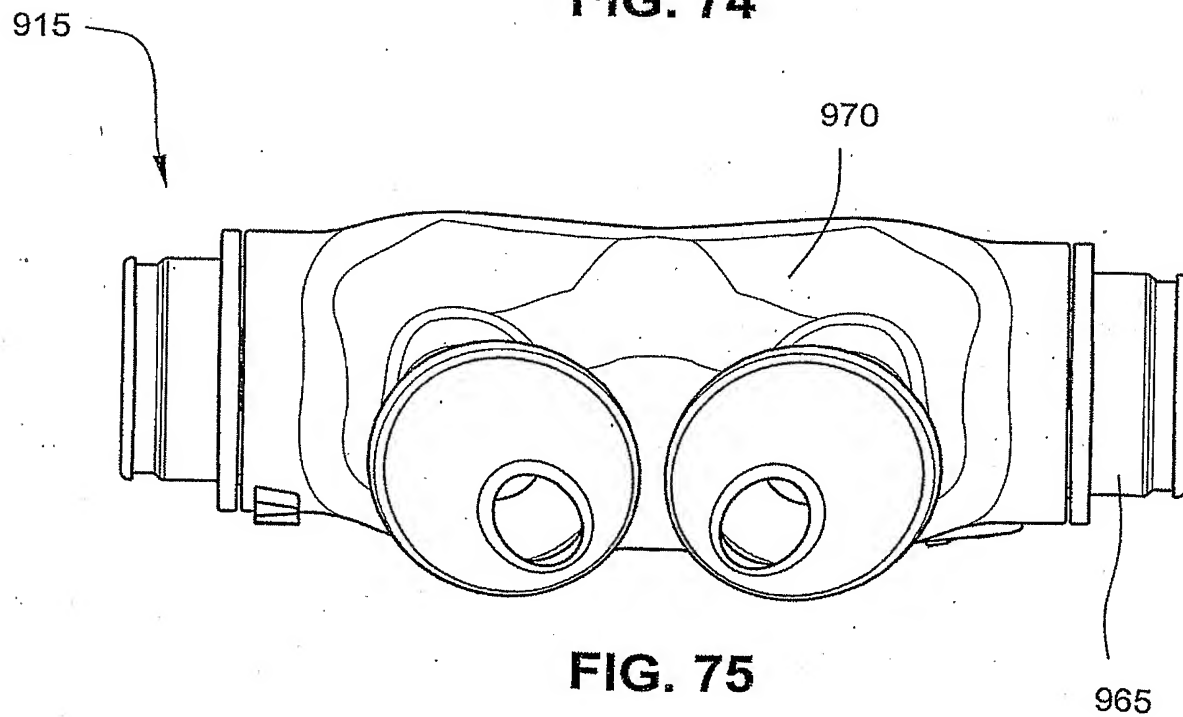


FIG. 75

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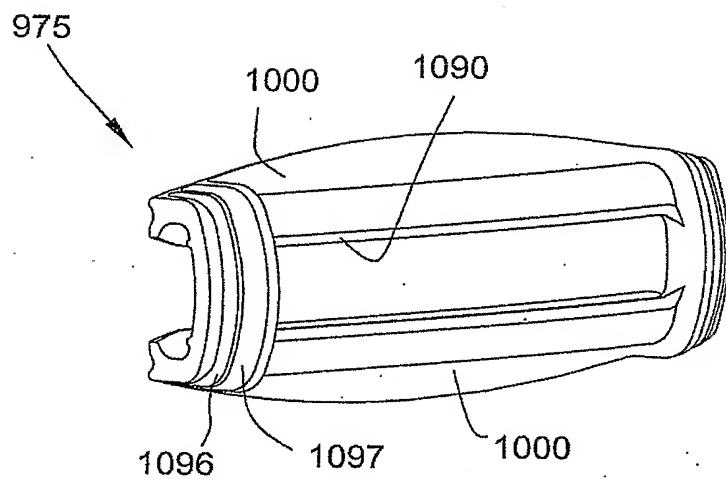


FIG. 76

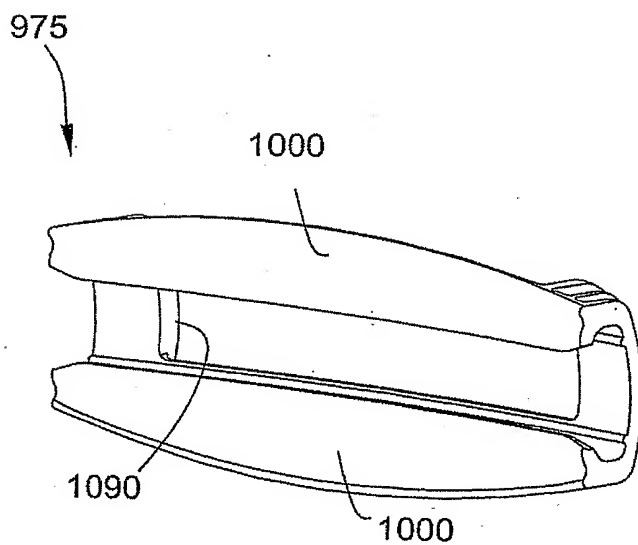


FIG. 77

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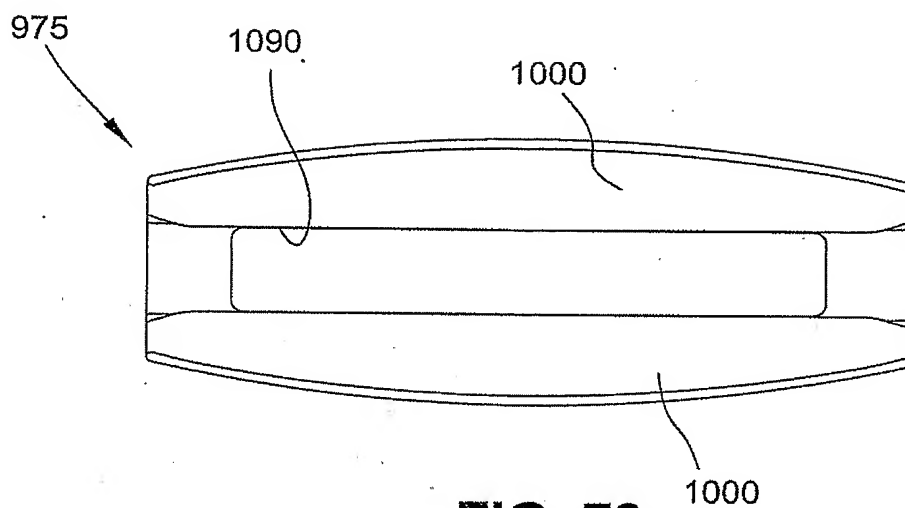


FIG. 78

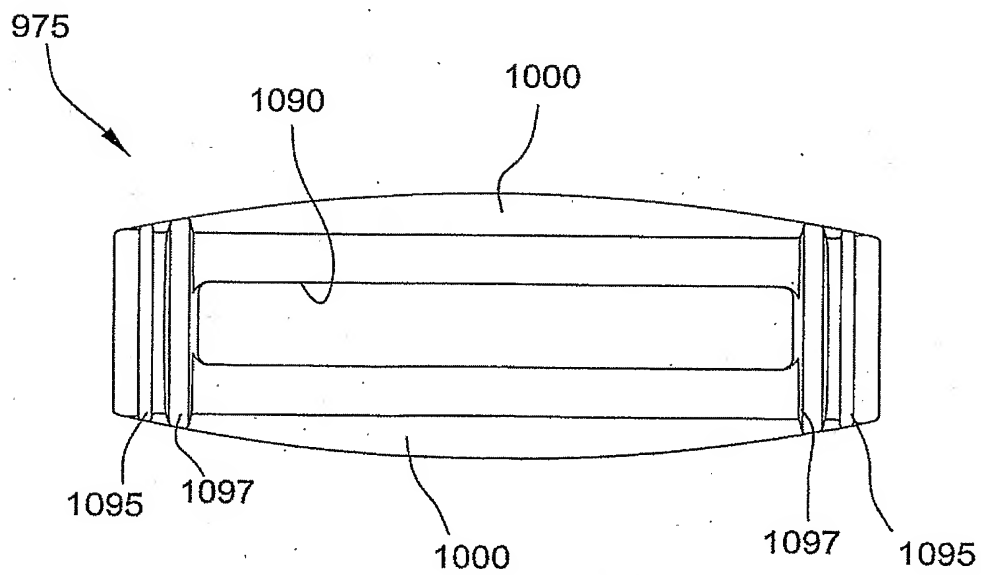


FIG. 79

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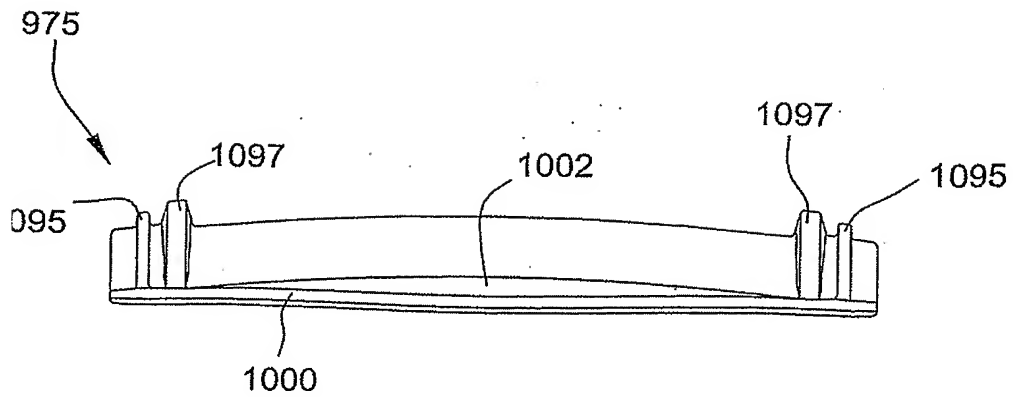


FIG. 80

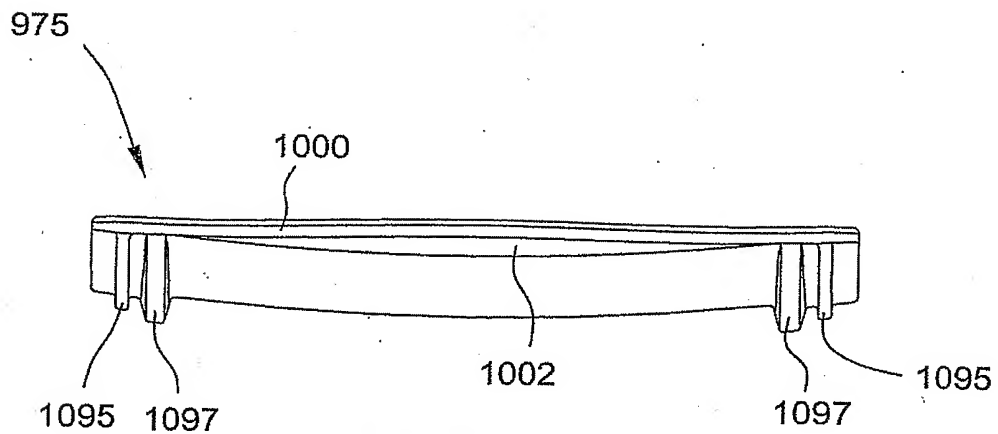


FIG. 81

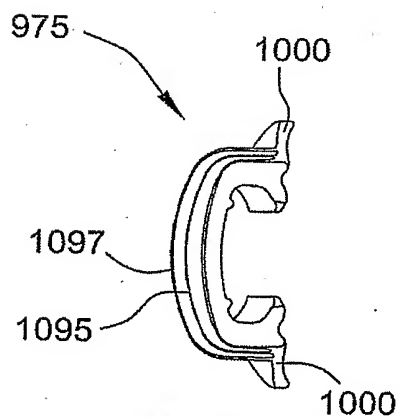


FIG. 82

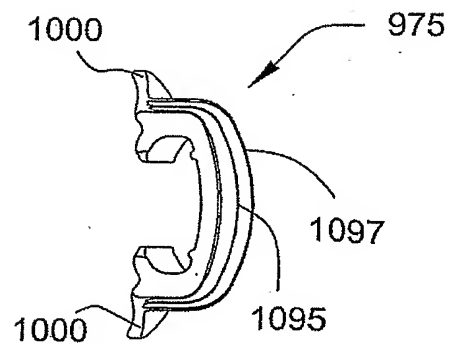
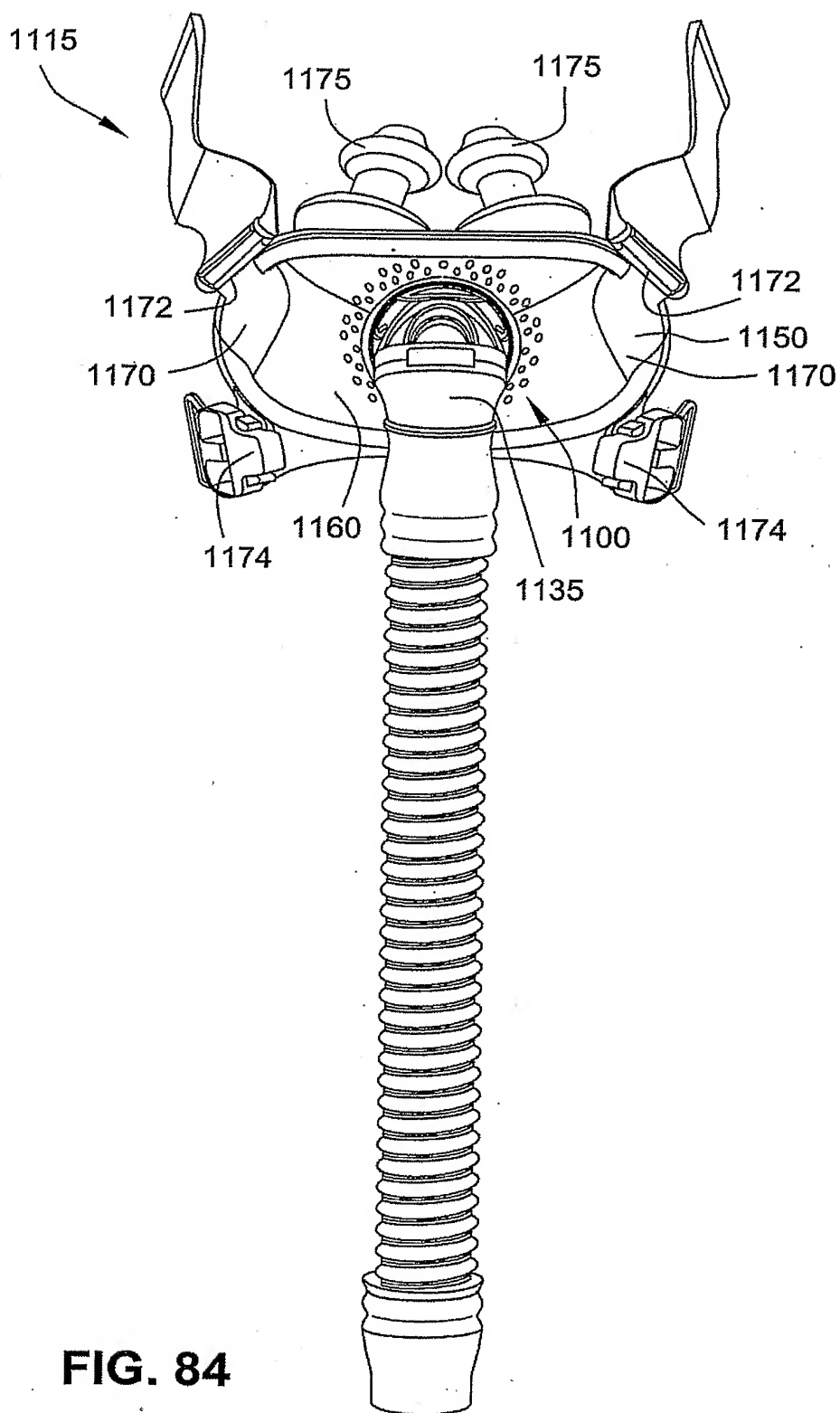


FIG. 83

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**FIG. 84**

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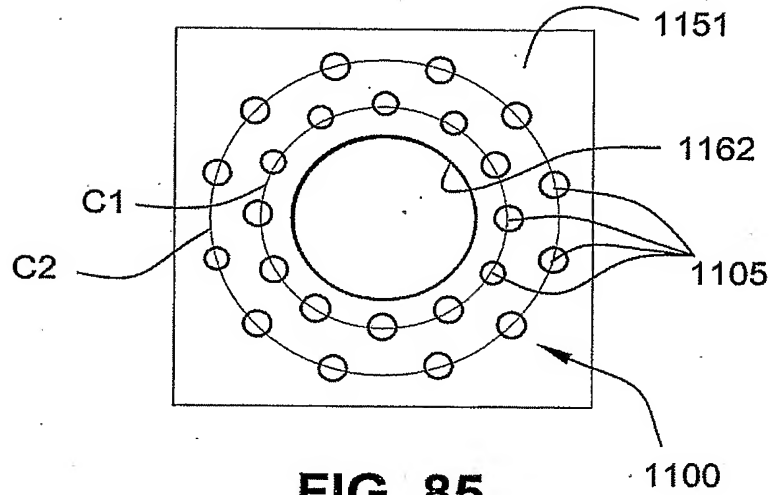


FIG. 85

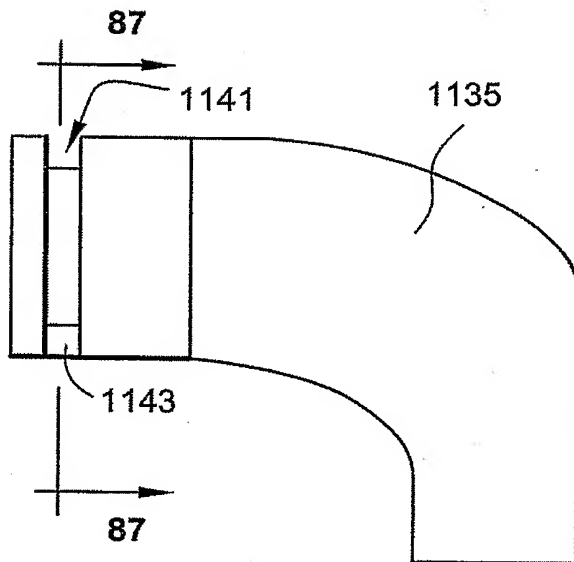


FIG. 86

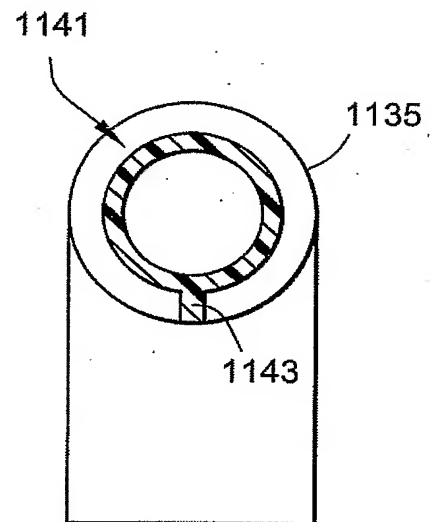


FIG. 87

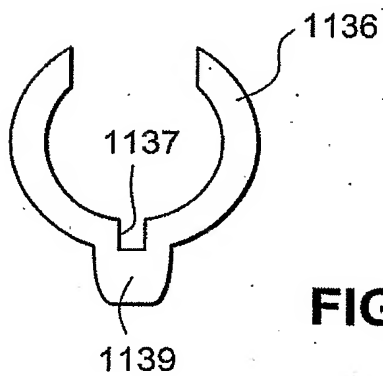


FIG. 88

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001507

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. <i>A61M 16/06</i> (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI IPC A61M, A62B +keywords: mask, vent, aperture and similar terms		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2002/066105 A (RESMED LTD) 29 August 2002 Figure 4 and page 6 lines 18 to 26	36, 38, 49, 67
A	US 3,850,171 A (BALL et al) 26 November 1974 Figure 1	
A	GB 880,824 A (OXYGENAIRE) 25 October 1961 Figure 2	
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search 09 January 2007		Date of mailing of the international search report 16 JAN 2007
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer Xavier Gisz Telephone No : (02) 6283 2064

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001507

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Extra Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 13-22, 36-51 and 67-82

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001507

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

- Claims 13-22, 36-51 and 67-82 are directed to a patient interface including a vent assembly wherein the plurality of vent holes are arranged in an offset fashion. It is considered that a nasal assembly including a plurality of vent holes arranged in an offset fashion comprises a first distinguishing feature.
- Claims 1-12 are directed to a nasal assembly including a single vent hole in the base wall of the vent channel. It is considered that a single vent hole in the base wall of the vent channel comprises a second distinguishing feature.
- Claims 23-25 are directed to a nasal assembly including a frame with cushion channels to receive the cushion. It is considered that a frame with cushion channels to receive a cushion comprises a third distinguishing feature.
- Claims 26-35 are directed to a nasal assembly including a clip to secure the cushion to the frame. It is considered that a clip to secure the cushion to the frame comprises a fourth distinguishing feature.
- Claims 52-66 are directed to a full-face mask frame including a vent assembly wherein a column of vent holes is aligned with the longitudinal axis of the mask frame. It is considered that a full-face mask frame including a vent assembly wherein a column of vent holes is aligned with the longitudinal axis of the mask frame comprises a fifth distinguishing feature.
- Claims 83-93 are directed to a nasal assembly including a cushion with indicia to provide a visual cue to assist the patient in achieving correct alignment. It is considered that indicia to assist the patient in achieving correct alignment comprises a sixth distinguishing feature.
- Claims 86-93 are directed to a nasal assembly including a vent channel, wherein the side walls of vent channel are of variable wall thickness. It is considered variable wall thickness comprises a seventh distinguishing feature.
- Claim 94 is directed to a nasal assembly including vent channels that separate higher velocity air flow and directs this flow to a vent hole. It is considered that a vent channel that separates the higher velocity air flow and directs this flow to a vent hole comprises an eighth distinguishing feature.
- Claims 96-105 are directed to a mask frame including a plurality of vent holes which are arranged around an aperture. It is considered that a plurality of vent holes around the aperture comprises a ninth distinguishing feature.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.